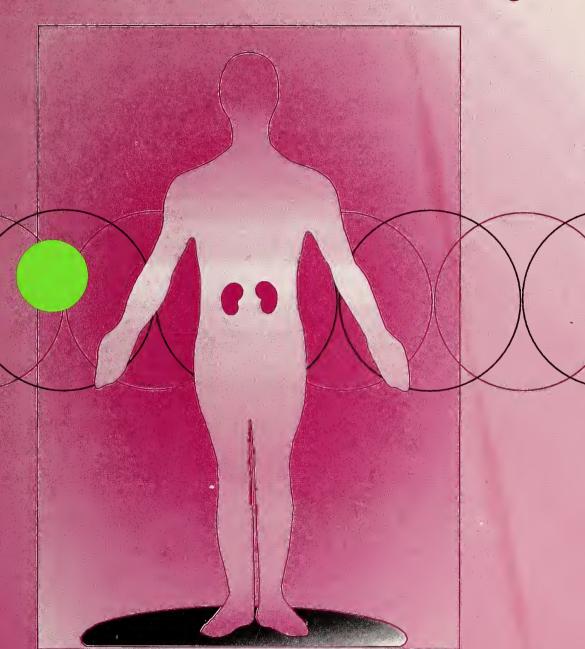
# 1997 Annual Report ESRD Core Indicators Project





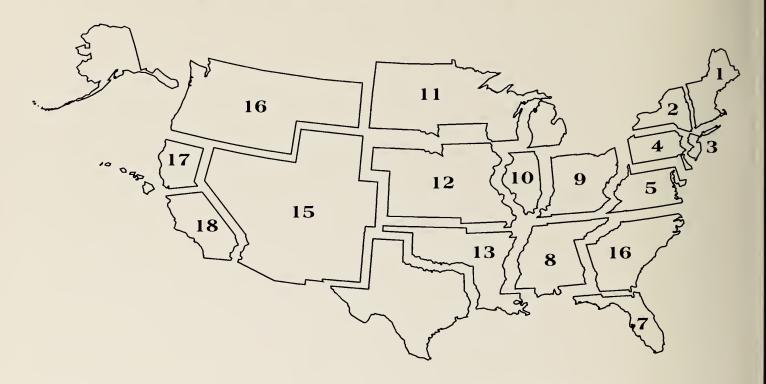
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Department of Health and Human Services Health Care Financing Administration Office of Clinical Standards and Quality

December 1997

## END STAGE RENAL DISEASE NETWORKS



ESRD Network No. 1 Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island

ESRD Network No. 2 New York State

ESRD Network No. 3 New Jersey, Puerto Rico, U.S. Virgin Islands

ESRD Network No. 4 Pennsylvania, Delaware

ESRD Network No. 5 District of Columbia, Maryland, Virginia, West Virginia

ESRD Network No. 6 Georgia, North Carolina, South Carolina

ESRD Network No. 7 Florida

ESRD Network No. 8 Alabama, Mississippi, Tennessee

ESRD Network No. 9 Kentucky, Indiana, Ohio

ESRD Network No. 10 Illinois

ESRD Network No. 11 Michigan, Minnesota, Wisconsin, North Dakota, South Dakota

ESRD Network No. 12 Missouri, Iowa, Nebraska, Kansas

ESRD Network No. 13 Arkansas, Louisiana, Oklahoma

ESRD Network No. 14 Texas

ESRD Network No. 15 New Mexico, Colorado, Wyoming, Utah, Arizona, Nevada

ESRD Network No. 16 Montana, Alaska, Idaho, Oregon, Washington

ESRD Network No. 17 Northern California, Hawaii, Pacific Trust Territory, Guam, American Samoa

ESRD Network No. 18 Southern California



JAN 22 1998

7500 SECURITY BOULEVARD BALTIMORE MD 21244-1850

#### Dear Dialysis Provider:

The Health Care Financing Administration (HCFA) and the End Stage Renal Disease (ESRD) Networks are pleased to provide you with a copy of the fourth annual report describing the results of the 1997 ESRD Core Indicators Project. This report provides a "snap-shot" description of the adult in-center hemodialysis population for the last calendar quarter of 1996 and the peritoneal dialysis population for the time period November-December, 1996 and January-April, 1997, for several "core" quality indicators. These indicators include measures of adequacy of dialysis, hematocrit levels, and serum albumin levels. The report also provides a comparison of the core indicators results from the last quarters of 1994, 1995, and 1996 for all 18 ESRD Networks that participated in the project. The data collected for this project by more than 2,000 dialysis facilities such as yours have made this report possible.

Please review the information in the report and examine your own care processes.

What percentage of hemodialysis and/or peritoneal dialysis patients at your facility are receiving adequate dialysis? What percentage of your patients have hematocrits > 30%? How do these indicators of care for your patients compare to the indicators described in the 1997 Annual ESRD Core Indicators Report? What improvements have been achieved at your facility since the 1996 ESRD Core Indicators Project Report?

These data should stimulate you to ask and answer questions such as these and, where indicated, to develop ways to improve care to your patients. Your ESRD Network is available to assist you in developing and implementing improvement strategies.

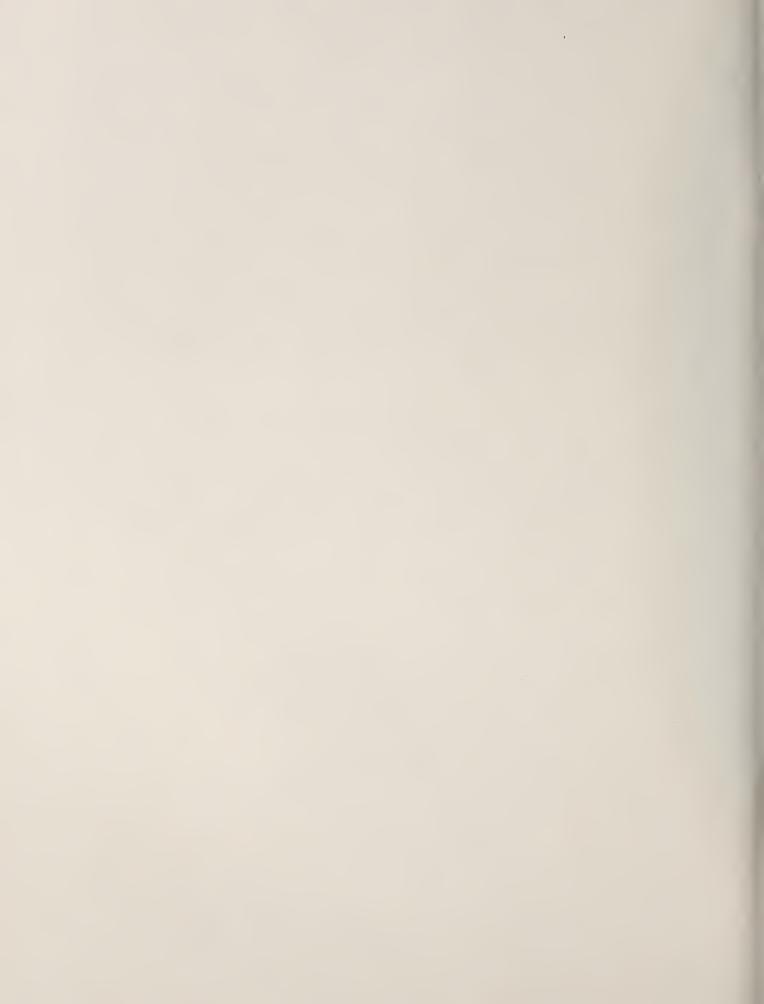
This report, as well as other data reports, is available on the Internet at www.hcfa.gov/medicare/hsqb/hsqb6c/htm. We ask that you take the time to review these reports and provide us with feedback as to their usefulness and ways you would like to see the clinical data displayed. We believe that by working together we will serve our mutual interest of improving the quality of care for dialysis patients.

Sincerely,

Peter Bouxsein Acting Director

Office of Clinical Standards and Quality

Enclosure



# 1997 ANNUAL REPORT

# ESRD CORE INDICATORS PROJECT

# OPPORTUNITIES TO IMPROVE CARE FOR ADULT IN-CENTER HEMODIALYSIS and PERITONEAL DIALYSIS PATIENTS

## **DECEMBER 1997**



Department of Health and Human Services Health Care Financing Administration Office of Clinical Standards and Quality Baltimore, Maryland



Suggested citation for this report is as follows:

Health Care Financing Administration. 1997 Annual Report, End Stage Renal Disease Core Indicators Project. Department of Health and Human Services, Health Care Financing Administration, Office of Clinical Standards and Quality, Baltimore, Maryland, December, 1997.

Note: The clinical data collected for the 1997 ESRD Core Indicators Project were from the time period of October, November, and December, 1996 for the hemodialysis patients and the time period November - December, 1996 and January - April, 1997 for the peritoneal dialysis patients.

Look for this report, as well as other ESRD Core Indicators Project Reports on the Internet at: www.hcfa.gov/medicare/hsqb/hsqb3c/htm

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## TABLE OF CONTENTS

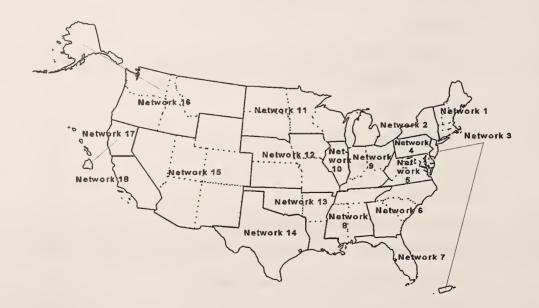
<b>SECTION</b>	TITLE	<u>PAGE</u>
	Table of Contents	3
	Acknowledgments	4
	List of Tables/Figures	5
I.	BACKGROUND	9
II.	PROJECT METHOD	9
III.	INITIAL ANALYSIS	11
IV.	IMPROVEMENT AND OPPORTUNITIES TO IMPROVE CARE	I4
V.	NEXT STEPS	17
VI.	HEMODIALYSIS PATIENTS	18
	A. Synopsis	18
	B. Adequacy of Dialysis	19
	C. Anemia Management	28
	D. Serum Albumin	38
VII.	PERITONEAL DIALYSIS PATIENTS	41
	A. Synopsis	41
	B. Adequacy of Dialysis	42
	C. Anemia Management	42
	D. Serum Albumin	46
	E. Blood Pressure Control	48
VIII.	IMPORTANT NOTE	50
IX.	APPENDICES	5 I
	1. ESRD Core Indicators Workgroup Members	51
	2. HCFA Offices and ESRD Networks	53
	3. I997 Core Indicators Data Collection Form - HD	55
	4. 1997 Core Indicators Data Collection Form - PD	57
	5. References	61

#### **ACKNOWLEDGMENTS**

The Health Care Financing Administration (HCFA) wishes to acknowledge the following groups and persons without whose efforts this report would not have been possible.

- The members of the End Stage Renal Disease (ESRD) Core Indicators Workgroup and the members of the Peritoneal Dialysis Subcommittee (see Appendix 1).
- The eighteen ESRD Network Organizations throughout the United States (see Appendix 2).
- The following HCFA Central Office staff: Darrel Grant, Debbie Grossblatt, Linda Okimoto, George Kattakuzhy, Ron Zeman and Bob Burger.
- Staff at more than 2,000 dialysis facilities in the United States who abstracted the requested information from medical records on more than 7,000 adult in-center hemodialysis and peritoneal dialysis patients.
- The many other individuals in the renal community and HCFA who contributed to this work.

FIGURE 1. Geographic Boundaries of the 18 ESRD Network Organizations.



#### LIST OF TABLES

<b>TABLE</b>	TITLE	<u>PAGE</u>
1.	Number of adult (aged ≥18 years), in-center hemodialysis patients in each Network in December 1996, sample size and response rate for the 1997 ESRD Core Indicators Project.	12
2.	Characteristics of adult (aged ≥18 years), in-center hemodialysis patients in the 1997 ESRD Core Indicators Project compared to those of all in-center hemodialysis patients in the U.S. in 1995.	13
3.	Number of adult (aged ≥ 18 years), peritoneal dialysis patients in each Network's sample and response rate for the 1997 ESRD Core Indicators Project.	13
4.	Characteristics of adult (aged $\geq$ 18 years), peritoneal dialysis patients in the 1997 ESRD Core Indicators Project.	14
5.	Mean URR, mean Kt/V, and percent of adult (aged $\geq$ 18 years), in-center hemodialysis patients with URR $\geq$ 65% and Kt/V $\geq$ 1.2, October - December 1996, by patient characteristics. 1997 ESRD Core Indicators Project.	20
ба.	Percent of adult (aged ≥18 years), in-center hemodialysis patients receiving dialysis with a mean URR ≥ 65%, October-December 1996, by patient characteristics and Network. 1997 ESRD Core Indicators Project.	22
6b.	Percent of adult (aged≥18 years), in-center hemodialysis patients receiving dialysis with a mean Kt/V ≥ 1.2 in October-December 1996, by patient characteristics and Network. 1997 ESRD Core Indicators Project.	23
7.	Mean time on dialysis for adult (aged ≥18 years), in-center hemodialysis patients in the U.S., October-December 1996, by patient characteristics. 1997 ESRD Core Indicators Project.	25
8.	Independent logistic regression analyses by selected patient and practice characteristics to predict Odds Ratio (95% CI) for hemodialysis with Kt/V < 1.2. 1997 ESRD Core Indicators Project.	28
9.	Hematocrit values for adult (aged ≥ 18 years), in-center hemodialysis patients in the U.S., October-December 1996, by patient characteristics. 1997 ESRD Core Indicators Project.	30
10a.	Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with hematocrit values between 33-36%, October-December 1996, by age, race, and Network. 1997 ESRD Core Indicators Project.	31
10b.	Percent of adult (aged ≥18 years), in-center hemodialysis patients with hematocrit values > 30%, October-December 1996, by age, race, and Network. 1997 ESRD Core Indicators Project.	32
11.	Percent of adult (aged ≥18 years), in-center hemodialysis patients in the U.S. receiving Epoetin at time hematocrit was drawn and the average Epoetin dose, October-December 1996, by patient characteristics. 1997 ESRD Core Indicators Project.	34
12.	Regional variation for various anemia management measures for adult (aged ≥ 18 years), in-center hemodialysis patients, October-December 1996, national and by Network. 1997 ESRD Core Indicators Project.	35
13.	Serum albumin values (gm/dL) for adult (aged ≥ 18 years), in-center hemodialysis patients in the U.S., October-December 1996, by patient characteristics and by laboratory method. 1997 ESRD Core Indicators Project.	38

#### LIST OF TABLES (continued)

14. Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with serum albumin > 40 3.5 gm/dL (BCG method) or ≥3.2 gm/dL (BCP method), October-December 1996, by age. race, and Network. 1997 ESRD Core Indicators Project. 15a. Percent of adult (aged ≥ 18 years) peritoneal dialysis patients with hematocrit values between 43 33% and 36%, Nov '96-Apr '97. 1997 ESRD Core Indicators Project. Hematocrit values for adult (aged > 18 years), peritoneal dialysis patients, Nov '96 - Apr 15b. 44 '97, by patient characteristics. 1997 ESRD Core Indicators Project. 16. Various anemia management measures for adult (aged ≥ 18 years), peritoneal dialysis 45 patients, Nov '96 - Apr '97, by patient characteristics. 1997 ESRD Core Indicators Project. 17. Mean and percent of adult (aged > 18 years), peritoneal dialysis patients with serum 47 albumin > 3.5 gm/dL (BCG method) or > 3.2 gm/dL (BCP method), Nov'96 - Apr '97, by patient characteristics. 1997 ESRD Core Indicators Project. Mean blood pressure (BP) value and percent of adult (aged > 18 years), peritoneal 49 18. dialysis patients with systolic BP > 150 mmHg or diastolic BP > 90 mmHg, Nov '96-Apr'97, by patient characteristics. 1997 ESRD Core Indicators Project.

#### LIST OF FIGURES

<b>FIGURE</b>	<u>TITLE</u>	<b>PAGE</b>
1.	Geographic Boundaries of the 18 ESRD Network Organizations.	4
2.	Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65% in October-December 1996 compared to October-December 1993, 1994, and 1995. 1997 ESRD Core Indicators Project.	15
3.	Distribution of URR values for adult (aged ≥18 years), in-center hemodialysis patients, October-December 1996 compared to October-December 1993, 1994, and 1995. 1997 ESRD Core Indicators Project.	15
4.	Percent of adult (aged≥18 years), in-center hemodialysis patients with mean hematocrit > 30% in October-December 1996 compared to October-December 1993, 1994, and 1995. 1997 ESRD Core Indicators Project.	16
5.	Distribution of hematocrit values for adult (aged ≥18 years), in-center hemodialysis patients, October-December 1996 compared to October-December 1993, 1994 and 1995. 1997 ESRD Core Indicators Project.	16
6.	Distribution of hematocrit values for adult (aged ≥18 years), peritoneal dialysis patients, Nov '96-Apr '97 compared to Nov '94-Apr '95, and Nov '95-Apr '96. 1997 ESRD Core Indicators Project.	17
7.	Distribution of mean URR values for adult (aged ≥18 years), in-center hemodialysis patients, October-December 1996. 1997 ESRD Core Indicators Project.	19
8.	Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65%, October-December 1996, by race and gender. 1997 ESRD Core Indicators Project.	20
9.	Percent of adult (aged $\ge 18$ years), in-center hemodialysis patients receiving dialysis with a mean URR $\ge 65\%$ , October-December 1996, by age group. 1997 ESRD Core Indicators Project.	21

#### LIST OF FIGURES (continued)

10.	Percent of adult (aged ≥18 years), in-center hemodialysis patients receiving dialysis with a mean URR ≥65%, October-December 1996, by diagnosis. 1997 ESRD Core Indicators Project.	21
11.	Percent of adult (aged ≥18 years), in-center hemodialysis patients receiving dialysis with a mean URR ≥65%, October-December 1996, by Network. 1997 ESRD Core Indicators Project.	24
12.	Percent of adult (aged ≥18 years), in-center hemodialysis patients receiving dialysis with a mean URR ≥ 65%, October-December 1996, by Network. 1997 ESRD Core Indicators Project.	24
13.	Distribution of time on dialysis (minutes) for adult (aged ≥18 years), in-center hemodialysis patients in the U.S., October-December 1996. 1997 ESRD Core Indicators Project.	25
14.	Percent of adult (aged ≥18 years), in-center hemodialysis patients with mean URR ≥65% in October-December 1996 compared to October-December 1993, 1994, and 1995, by race. 1997 ESRD Core Indicators Project.	26
15.	Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65% in October-December 1996, by dialyzer KUf value compared to October-December 1993, 1994, and 1995. 1997 ESRD Core Indicators Project.	26
16.	Distribution of dialysis session length (minutes) in October-December 1996 compared to October-December 1993, 1994, and 1995. 1997 ESRD Core Indicators Project.	26
17.	Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65%, October-December 1996 compared to October-December 1993, 1994, and 1995, by Network. 1997 ESRD Core Indicators Project.	27
18.	ESRD Network areas with statistically significant improvement in percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65% in October-December 1996 compared to October-December 1993, 1994, and 1995. 1997 ESRD Core Indicators Project.	27
19.	Distribution of mean hematocrit values for adult (aged ≥ 18 years), in-center hemodialysis patients in the U.S., October-December 1996, by race. 1997 ESRD Core Indicators Project.	29
20.	Percent of adult (aged ≥18 years), in-center hemodialysis patients with mean hematocrit between 33-36%, October-December 1996, by age and race. 1997 ESRD Core Indicators Project.	29
21.	Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean hematocrit > 30%, October-December 1996, by Network. 1997 ESRD Core Indicators Project.	33
22.	Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean hematocrit > 30%, October-December 1996, by Network. 1997 ESRD Core Indicators Project.	33
23.	Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean hematocrit >30%, October-December 1996 compared to October-December 1993, 1994, and 1995, by race. 1997 ESRD Core Indicators Project.	36
24.	Percent of adult (aged ≥18 years), in-center hemodialysis patients with severe anemia (hematocrit < 25%), by race, October-December 1996 compared to October-December 1993, 1994, and 1995. 1997 ESRD Core Indicators Project.	36
25.	Percent of adult (aged ≥18 years), in-center hemodialysis patients with mean hematocrit > 30%, in October-December 1996 compared to October-December 1993, 1994, and 1995, by Network. 1997 ESRD Core Indicators Project.	37

#### LIST OF FIGURES (continued)

26.	Mean Epoetin dose (units/kg) for adult (aged ≥ 18 years), in-center hemodialysis patients, by hematocrit category, October-December 1996 compared to October - December 1994, and 1995. 1997 ESRD Core Indicators Project.	37
27.	Distribution of serum albumin values for adult (aged ≥18 years), in-center hemodialysis patients, October-December 1996, by laboratory method. 1997 ESRD Core Indicators Project.	39
28.	Percent of adult (aged $\ge 18$ years), in-center hemodialysis patients with mean serum albumin $\ge 3.5$ gm/dL (BCG method) or $\ge 3.2$ gm/dL (BCP method), October-December 1996, by race and gender. 1997 ESRD Core Indicators Project.	39
29.	Percent of adult (aged $\ge 18$ years), in-center hemodialysis patients with mean serum albumin values $\ge 3.5$ gm/dL (BCG method) or $\ge 3.2$ gm/dL (BCP method), October-December 1996 compared to October-December, 1993, 1994, and 1995. 1997 ESRD Core Indicators Project.	39
30.	Distribution of hematocrit values for adult (aged ≥ 18 years), peritoneal dialysis patients, Nov '96-Apr '97, by race. 1997 ESRD Core Indicators Project.	43
31.	Percent of adult (aged ≥ 18 years), peritoneal dialysis patients with mean hematocrit > 30%, Nov'96-Apr'97 compared to Nov'94-Apr'95 and Nov'95-Apr'96. 1997 ESRD Core Indicators Project.	43
32.	Percent of adult (aged≥18 years), peritoneal dialysis patients with severe anemia (hematocrit < 25%), by race, Nov'96-Apr'97 compared to Nov '94-Apr '95 and Nov '95-Apr '96. 1997 ESRD Core Indicators Project.	46
33.	Mean Epoetin dose (units/kg) by hematocrit category for adult (aged≥18 years) peritoneal dialysis patients, Nov'96-Apr'97 compared to Nov '94-Apr '95 and Nov '95-Apr '96. 1997 ESRD Core Indicators Project.	46
34.	Distribution of serum albumin values for adult (aged≥18 years), peritoneal dialysis patients, Nov'96-Apr'97, by laboratory method. 1997 ESRD Core Indicators Project.	48
35.	Percent of adult (aged $\geq$ 18 years), peritoneal dialysis patients with mean serum albumin $\geq$ 3.5 gm/dL (BCG method) or $\geq$ 3.2 gm/dL (BCP method), Nov'96-Apr'97, by race and gender. 1997 ESRD Core Indicators Project.	48-
36.	Percent of adult (aged $\geq$ 18 years), peritoneal dialysis patients with mean serum albumin $\geq$ 3.5 gm/dL (BCG method) or $\geq$ 3.2 gm/dL (BCP method), Nov'96-Apr'97 compared to Nov '94-Apr '95 and Nov '95-Apr '96. 1997 ESRD Core Indicators Project.	48
37.	Distribution of systolic blood pressure values for adult (aged ≥18 years), peritoneal dialysis patients, Nov '96-Apr '97. 1997 ESRD Core Indicators Project.	49
38.	Distribution of diastolic blood pressure values for adult (aged ≥18 years), peritoneal dialysis patients, Nov '96-Apr '97. 1997 ESRD Core Indicators Project.	49
39.	Percent of adult (aged ≥18 years), peritoneal dialysis patients with mean blood pressure values > 150 mmHg (systolic) or > 90 mmHg (diastolic), Nov '96-Apr '97. 1997 ESRD Core Indicators Project.	50

#### 1997 ESRD Core Indicators Project

#### I. BACKGROUND

The Social Security Amendments of 1972 (P.L. 92-603) extended Medicare coverage to individuals with ESRD who require dialysis or a kidney transplant to maintain life. To qualify for Medicare under the renal provision a person must have ESRD and either: be entitled to a monthly insurance benefit under Title II of the Social Security Act (or an annuity under the Railroad Retirement Act); or be fully or currently insured under Social Security; or be the spouse or dependent child of a person who meets at least one of these last two requirements. There is no minimum age for eligibility under the renal disease provision. The incidence of treated ESRD in the United States is 180 per million population and continues to rise at a rate of 7.8 percent per year. (1) As of December 31, 1996, there were 214,103 patients receiving dialysis therapy in the United States. (2)

There are 18 ESRD Network Organizations throughout the United States that are under contract to HCFA to perform oversight activities to assure the appropriateness of services and protection for ESRD patients. In 1994, HCFA, with input from the renal community, reshaped the ESRD Network program's approach to quality assurance and improvement in order to respond to the need to improve the care of Medicare ESRD patients. (3) This approach has been named the ESRD Health Care Quality Improvement Program (HCQIP).

The ESRD HCQIP gives the ESRD Networks and HCFA a chance to demonstrate that health care provided to renal Medicare beneficiaries can be measurably improved. The HCQIP is based on the assumption that most health care providers need and welcome both information and, where necessary, help in applying the tools and techniques of quality management. (4)

The ESRD Core Indicators Project is HCFA's first nationwide population-based study to assess and identify opportunities to improve the care of patients with ESRD. (5) This project has established a consistent clinical database. The elements included in the database represent clinical measures felt to be indicative of key components of care surrounding

dialysis. As such, the data points are considered "indicators" for use in triggering improvement activities.

HCFA and the ESRD Networks are committed to improving ESRD patient care and outcomes by providing tools that can be used by the renal community in assessing patient care processes and outcomes and identifying opportunities for improvement. One of these tools includes data feedback reports based on the clinical information obtained from the ESRD Core Indicators Project. We invite the renal community to provide us with ideas and feedback as to ways HCFA and the Networks can best help the community improve patient care.

#### II. PROJECT METHOD

The purpose of the ESRD Core Indicators Project is to provide comparative data to ESRD care givers to assist them in assessing and improving the care provided to ESRD patients. Data collected in 1994 established baseline estimates for October-December, 1993 for important clinical measures of care for adult, in-center hemodialysis patients in the U.S. (6) In 1995, data were collected on adult, incenter hemodialysis patients for October-December, 1994 and also on peritoneal dialysis patients for November, December, 1994 and January - April, 1995. (7, 8)

The third core indicators data collection effort was conducted in 1996 (9) to determine if patterns in these clinical measures had changed and if opportunities to improve care continued to exist. The fourth data collection effort (which is the subject of this report), conducted in 1997, examined data from October-December 1996 for in-center hemodialysis patients and from November, December, 1996 and January-April, 1997 for peritoneal dialysis patients in order to identify further opportunities to improve care.

#### The Sample

In February, 1997, using HCFA's Renal Beneficiary and Utilization System (REBUS) data system, we identified all in-center hemodialysis and peritoneal dialysis patients that met the following criteria: ≥ 18 years of age as of September 30, 1996; and alive on December 31, 1996. Using the REBUS data system, we were able to obtain the following information for each applicable patient: last name, first name, middle initial, date of birth, gender, race, Social Security Number and/or Health Insurance Claim number, underlying etiology of ESRD, the date that dialysis was initiated and the provider number of the facility where the patient was dialyzing.

From this universe of patients we selected a random sample of in-center hemodialysis patients, stratified by Networks and a national random sample of peritoneal dialysis patients. The hemodialysis patient sample size was determined by our desire to be 95% confident that Network-specific estimates for selected clinical measures be accurate within +/-5%. We over sampled by 10% to compensate for an anticipated non-response rate. The final sample consisted of 7,292 in-center hemodialysis patients and 1,375 peritoneal dialysis patients.

#### **Data Collection**

A one page hemodialysis and a two page peritoneal dialysis data collection form were used (Appendices 3 & 4); the use of these forms was authorized through the National Institutes of Health clinical exemption process. Descriptive information on each selected patient was printed onto gummed labels which were placed on the appropriate data collection forms before the forms were sent to individual ESRD facilities to be completed. If demographic (e.g. name, date of birth, or race) or clinical (e.g. diagnosis of ESRD or date that initial dialysis occurred) information was incorrect, facility staff were asked to correct the information. Staff at ESRD facilities were also asked to abstract ethnicity and clinical information from each selected patient's medical record.

In July, 1997, the data collection forms for patients in the sample were distributed to ESRD facilities. Completed forms were returned to the appropriate Network where data were reviewed for acceptability and manually entered into an Epi Info, v.6.04a file.

(10) By September 1, 1997, each Network had sent a copy of the resulting Epi Info, v 6.04a file to HCFA Central Office in Baltimore where the data were aggregated for the initial analysis.

Clinical information in the selected patients' medical record was abstracted for each patient in the hemodialysis sample who was receiving in-center hemodialysis during the months of October, November, and December, 1996 and for each patient in the peritoneal dialysis sample who was receiving peritoneal dialysis during the two-month periods of November-December, 1996, January-February, 1997 and March-April, 1997. Please refer to the data collection forms contained in Appendices 3 and 4 for the clinical information that was abstracted on each patient (in-center hemodialysis and peritoneal dialysis) included in the study.

#### **Core Indicators**

Using the clinical information abstracted by facility staff, we were able to describe the prevalence of several conditions of care which we call core indicators. The core indicators used in this project were identified by a workgroup (see Appendix 1) composed of representatives from the renal community, the ESRD Networks and HCFA. The core indicators identified were:

1. Adequacy of Dialysis: as measured by the urea reduction ratio (URR) and/or Kt/V for in-center hemodialysis patients: and weekly Kt/V and/or weekly creatinine clearance for peritoneal dialysis patients.

Based on the Renal Physicians Association clinical practice guideline, an NIH Consensus Conference statement, and the National Kidney Foundation's (NKF) Dialysis Outcome Quality Initiative (DOQI) Clinical Practice Guidelines for Hemodialysis Adequacy, the mean URR of 65% or more was defined as adequate hemodialysis. (1,11,12) The URR measurement of 65% is approximately equivalent to the Kt/V measurement of 1.2. (11,12) [URR = (pre-dialysis BUN minus post-dialysis BUN)/pre-dialysis BUN].

Based on the DOQI Clinical Practice Guidelines for Peritoneal Dialysis Adequacy, adequate dialysis for peritoneal dialysis patients is defined as a mean Kt/V of 2.1 for cyclers with daytime dwell, 2.2 for cyclers with out daytime dwell, and 2.0 for patients on Continuous Ambulatory Peritoneal Dialysis (CAPD). (13)

Findings from this project allow us to describe the mean URR and Kt/V values for hemodialysis patients in each Network area as well as the percent of hemodialysis patients in the U.S. with a delivered URR > 65%.

2. Anemia Management: as measured by the hematocrit level for both in-center hemodialysis and peritoneal dialysis patients. Findings from this project allow us to describe the mean hematocrit values for hemodialysis patients in each Network area and nationally for peritoneal dialysis patients. We are also able to describe the percent of patients with mean hematocrit values > 30% and the percent of patients with mean hematocrits between 33% - 36%, the target range recommended by the DOQI Clinical Practice Guidelines for the Treatment of Anemia. (14)

Each monthly recorded hematocrit was used in determining the percent of patients receiving Epoetin, and the average weekly Epoetin dose stratified by hematocrit levels.

3. <u>Serum Albumin</u>: Serum albumin level was chosen as an indicator for assessing mortality risk for adult in-center hemodialysis and peritoneal dialysis patients. Serum albumin values are described separately for those patients whose blood was tested by the bromcresol green (BCG) method or by the bromcresol purple (BCP) method. These two commonly used methods for determining serum albumin concentrations have been reported to yield systematically different results; the BCG method yielding higher serum albumin concentrations than the BCP method. (15)

Mean serum albumin values < 3.5 gm/dL by the BCG method were defined as an indicator of inadequate serum albumin levels. Since the percent of mean serum albumin values < 3.2 gm/dL by the BCP method was essentially the same as the percent of mean serum albumin values < 3.5 gm/dL by the BCG method, we also defined a BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin levels. Findings from this project allow us to describe the mean serum albumin value for hemodialysis patients in each Network area and nationally for peritoneal dialysis patients.

4. <u>Blood Pressure Levels</u>: for the peritoneal dialysis patient sample only, systolic and diastolic blood pressure values were abstracted for each two-month period to assess the control of blood pressure.

#### III. INITIAL ANALYSIS

#### Hemodialysis:

Initial analysis focused on three clinical measures: paired pre- and post-dialysis BUN values (used to calculate URR values); paired pre- and post-dialysis BUN values with patient height and weight and dialysis session length (used to calculate Kt/V values); hematocrit values; and serum albumin values. Inclusion of a case in the analysis required that data be available for at least one of the months in the three month project period, with three clinical measures being present. We were able to include for analysis 6,858 of the 7,292 patients from the sample (response rate=94%) (TABLE 1).

Characteristics regarding the gender, race, age, and diagnosis of ESRD for these patients are shown in Table 2. As expected, the characteristics of this random sample were very similar to the characteristics of the overall U.S. hemodialysis population. Data regarding Epoetin use, ferritin levels, transferrin saturation levels, iron use, Kt/V, KUf, and actual time on dialysis were also analyzed. The initial analysis utilized Epi Info and Statistical Package for the Social Sciences (SPSS) software. (10,16)

For this report each patient's mean monthly value for the three month project period was determined from the available data for the following items: URR, Kt/V, time on dialysis, KUf, hematocrit, and serum albumin. Because we had data from a stratified random sample of patients (i.e., a separate random sample from each of the 18 Network areas), it was necessary to weight the collected data in order to obtain unbiased estimates of mean clinical values for the total population. This weighting was done according to the proportion of each Network's total population sampled. Aggregate national results shown in this report were derived from weighted data; Network-specific comparisons were derived from unweighted data.

#### Peritoneal Dialysis:

Initial analysis focused on the adequacy of dialysis, hematocrit values, serum albumin values and blood pressure control. Inclusion of a case for analysis required that the patient received peritoneal dialysis at least one of the two-month time periods from November 1996 - April 1997. 1,219 patients of the 1,375 patients from the sample were included for analysis (89% response rate) (TABLE 3). Selected patient characteristics of this sample for analysis are shown in Table 4.

For this report, each patient's mean value for the six month study period was determined from available data for the following items: hematocrit, serum albumin, systolic and diastolic blood pressure values, Epoetin dosing, ferritin levels, transferrin saturation levels, and iron use. The data are from a random sample, not stratified by Network, thus, only national aggregate data are reported. No Network specific analyses were conducted.

#### Report Format

This report describes the core indicators findings for both the hemodialysis patient sample and the peritoneal dialysis patient sample in separate sections, VI and VII respectively, for the following study period: October, November, December 1996 for the hemodialysis patients and November, December, 1996 and January-April 1997 for the peritoneal dialysis patients.

The national results are presented separately in tables by gender, race, age groups (18-44, 45-64, and 65+ years of age), and diagnosis of ESRD. The diagnoses are categorized as diabetes mellitus (DM), hypertension (HTN), glomerulonephritis (GN), and other/unknown. (17) In some instances clinical characteristics for patients in each Network area are also shown. Selected results are highlighted in figures.

In addition, key findings from the 1997 Core Indicators study (describing patterns of clinical measures from October-December, 1996) are compared to key findings from previous study periods.

TABLE 1: Number of adult (aged ≥ 18 years), in-center hemodialysis patients in each Network in Dec 1996, sample size and response rate for the 1997 ESRD Core Indicators Project.

Network	# HD Patients Dec 1996*	Sample Size	# Acceptable Forms^	Response Rate %
1	6,191	400	366	91.5
2	11,992	411	383	93.2
3	7,219	403	391	97.0
4	10,129	409	393	96.1
5	10,638	410	385	93.9
6	14,986	413	361	87.4
7	10,008	407	394	96.8
8	10,165	409	382	93.4
9	9,864	409	382	93.4
10	7,012	403	362	89.8
11	9,510	407	395	97.1
12	5,721	398	354	88.9
13	6,780	402	387	96.3
14	13,055	411	391	95.1
15	6,327	400	388	97.0
16	3,965	388	374	96.4
17	7,011	402	386	96.0
18	11,296	410	384	93.7
Total	161,869	7,292	6,858	94.0

<sup>\*</sup>Patient count numbers are from HCFA's REBUS Database

Two or more monthly values for these clinical measures were available for 96% of patients for hematocrit, 95% for serum albumin by either BCG or BCP method. Monthly hematocrit values were available for 89% of patients. At least one monthly paired pre-and post-dialysis BUN value was available for 97% of patients, and two or more were available for 82%. Monthly paired pre- and post-dialysis BUN values were available for 68% of patients.

<sup>^</sup> A form was considered acceptable if the patient met the selection criteria for inclusion in the study and if data were provided for at least one of the months in the fourth quarter of 1996, for the following items: 1) hematocrit; 2) paired pre- and post-dialysis BUN values; and 3) serum albumin value.

TABLE 2: Characteristics of adult (aged ≥18 years), incenter hemodialysis patients in the 1997 ESRD Core Indicators Project compared to those of all in-center hemodialysis patients in the U.S. in 1995.

Patient Characteristic	1997 Indica Samp Anal	ators le for	All U.S 1995	
	# ^	%	# in 1000s	%
TOTAL	6858	100	159.3	100
GENDER				
Men	3591	52	81.8	51
Women	3266	48	77.6	49
RACE/ETHNICITY				
American Indian/ Alaska Native	66	1	2.6	2
Asian/Pacific Islander	141	2	5.2	3
African-American	2509	37	62.9	39
Caucasian	3523	51	85.7	54
Other/Unknown	619	9	3.1	2
Hispanic	776	11		
AGE GROUP - years				
18-44	1243	18	27.6**	17
45-64	2532	37	57.3	36
65+	3083	45	73.6	46
DIAGNOSIS				
Diabetes mellitus	2617	38	56.7	36
Hypertension	1860	27	47.7	30
Glomerulonephritis	956	14	21.1	13
Other/Unknown	1425	21	33.8	21

<sup>\*</sup>USRDS: 1997 Annual Data Report, Bethesda, MD, National Institutes of Health, 1997

Note: Percents may not add up to 100% due to rounding

TABLE 3: Number of adult (aged ≥18 years), peritoneal dialysis patients in each Network's sample and response rate for the 1997 ESRD Core Indicators Project.

Network	Sample Size	# Acceptable Forms^	Response Rate %
1	62	53	85.5
2	93	82	88.2
3	72	69	95.8
4	98	83	84.7
5	93	82	88.2
6	131	104	79.4
7	55	51	92.7
8	54	51	94.4
9	123	114	92.7
10	53	38	71.7
11	102	99	97.1
12	84	65	77.4
13	44	42	95.5
14	76	71	93.4
15	54	49	90.7
16	41	39	95.1
17	53	51	96.2
18	87	76	87.4
Total	1,375	1,219	88.7

<sup>^</sup> A form was considered acceptable if the patient was receiving peritoneal dialysis at least one of the two-month periods during the six month study period and had met the selection criteria for inclusion in the study.

Two or more values over the six month study period for these clinical measures were available for 90% of patients for hematocrit and for serum albumin levels either by BCG or BCP method, and for 87% of patients for paired systolic and diastolic blood pressure values. Approximately 75% of patients had adequacy of dialysis assessed at least once during the six month study period.

<sup>\*\*</sup> For ages 20-44 years

<sup>^</sup> when subgroup totals do not equal 6858, due to missing data

TABLE 4: Characteristics of adult (aged ≥ 18 years), peritoneal dialysis patients in the 1997 ESRD Core Indicators Project.

Patient Characteristic	1997 C Indicat Sample Analy	tors for
	# ^	%
TOTAL	1219	100
GENDER		
Men	626	51
Women	593	49
RACE/ETHNICITY		
American Indian/ Alaska Native	2	0.2
Asian/Pacific Islander	17	1
African-American	297	25
Caucasian	795	66
Other/Unknown	94	8
Hispanic	115	9
AGE GROUP (years)		
18-44	332	27
45-64	551	45
65+	336	28
DIAGNOSIS		
Diabetes mellitus	421	34
Hypertension	270	22
Glomerulonephritis	216	18
Other/Unknown	312	26

 $<sup>^{\</sup>wedge}$  when subgroup totals do not equal 1219, due to missing data

Note: Percents may not add up to 100% due to rounding

# IV. IMPROVEMENTS AND OPPORTUNITIES TO IMPROVE CARE

By describing the prevalence of important clinical characteristics of adult, in-center hemodialysis patients in the U.S. in October-December 1993, October-December 1994, October-December 1995, and again in October-December 1996 this project has documented important improvements in and continuing opportunities to improve care for these patients.

Striking improvement in the adequacy of dialysis for in-center hemodialysis patients occurred. However, important opportunities to improve this care further remain.

In the last quarter of 1996, 68% of the sampled adult, in-center hemodialysis patients in the U.S. received dialysis which resulted in a URR > 65%. The percent of patients receiving dialysis at this URR level increased significantly from 59% to 68% from late 1995 to late 1996 (FIGURE 2). This represents a significant improvement in care, with approximately 40,000 more hemodialysis patients in the U.S. receiving dialysis with URR ≥ 65% in late 1996 than would have been receiving dialysis at this level in late 1993 (FIGURE 3). At the same time, approximately 30% of the patients were receiving dialysis with URR < 65%.

Another important improvement occurred in hematocrit levels of the sampled in-center hemodialysis patients. In late 1993, 46% of adult in-center hemodialysis patients in the 16 participating Networks had a mean hematocrit > 30%, by late 1996 this percent had increased to 72% (FIGURES 4,5). It should be noted that one goal of the National Anemia Cooperative Project is to increase the percent of patients with hematocrit > 30%. (18)

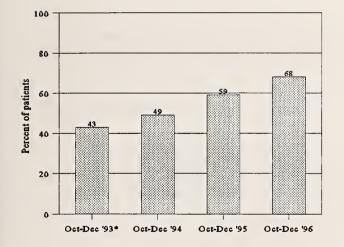
A similar improvement in hematocrit levels was also seen in the sampled peritoneal dialysis patients. The average hematocrit level for these patients in the 1995 study period was 32.5%, 33.1% in the 1996 study period and 33.8% in the 1997 study period. (Figure 6) The percentage of sampled peritoneal dialysis patients with a mean hematocrit level >30% was 63% in the 1995 study period, 70% in the 1996 study period and 76% in the 1997 study period.

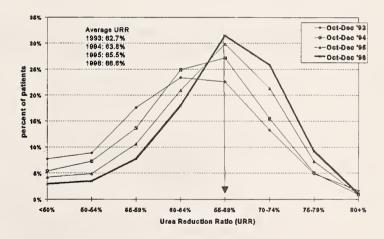
The purpose of this report is to provide you with an initial look at the Network and national pictures of the clinical measures that were collected for the ESRD Core Indicators Project. The project did not attempt to develop facility-specific profiles of care.

FIGURE 2: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65% in October - December 1996 compared to October - December 1993\*, 1994 and 1995. 1997 ESRD Core Indicators Project.

As you review this information, ask yourself: What percentage of adult patients at your facility are receiving adequate dialysis (URR  $\geq$  65% or Kt/V  $\geq$  1.2 for in-center hemodialysis patients)? What percentage of your patients have an average hematocrit  $\geq$  30%? How do these indicators of care for your patients compare to the indicators described in this report? We want this report to stimulate you to answer questions such as these and, where indicated, to develop ways to improve care to your patients.

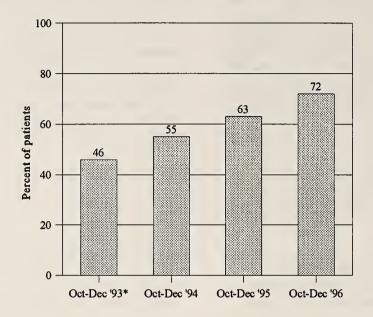
FIGURE 3: Distribution of URR values for adult (aged ≥ 18 years), in-center hemodialysis patients October - December 1996 compared to October-December 1993\*, 1994, and 1995. 1997 ESRD Core Indicators Project.





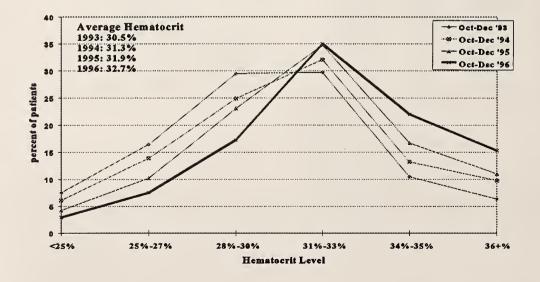
<sup>\*</sup> Sixteen Network area participated in the first ESRD Core Indicators assessment (Oct-Dec 1993); all Networks areas participated in subsequent years.

FIGURE 4: Percent of adult (aged≥18 years), in-center hemodialysis patients with mean hematocrit > 30% in October-December 1996 compared to October-December 1993\*, 1994, and 1995. 1997 ESRD Core Indicators Project.



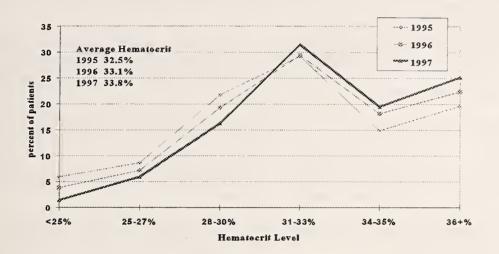
<sup>\*</sup> Sixteen Network area participated in the first ESRD Core Indicators assessment (Oct-Dec 1993); all Networks areas participated in subsequent years.

FIGURE 5: Distribution of hematocrit values for adult (aged ≥ 18 years), in-center hemodialysis patients, October-December 1996 compared to October-December 1993\*, 1994 and 1995. 1997 ESRD Core Indicators Project.



<sup>\*</sup> Sixteen Network area participated in the first ESRD Core Indicators assessment (Oct-Dec 1993); all Networks areas participated in subsequent years.

FIGURE 6: Distribution of hematocrit values for adult (aged ≥ 18 years), peritoneal dialysis patients, Nov '96-Apr '97 compared to Nov '94-Apr '95, and Nov '95-Apr '96. 1997 ESRD Core Indicators Project.



#### V. NEXT STEPS

Copies of the initial results of the 1997 ESRD Core Indicators Project will be distributed to all dialysis facilities for the purpose of stimulating facility efforts to improve care. Your Network staff and Medical Review Board will be available to assist you in identifying and developing improvement efforts.

As mentioned previously, while significant improvements have occurred, the opportunity to improve care for adult, in-center hemodialysis patients and peritoneal dialysis patients in the U.S. in the area of adequacy of dialysis continues to be striking. Every ESRD facility should be familiar with the clinical practice guidelines on adequacy of hemodialysis developed by the Renal Physicians Association (11) and the NKF's DOQI. (12,13)

Factors that contribute to the inadequate delivery of dialysis are discussed in these documents. Efforts to improve the adequacy of dialysis should be attentive to these factors.

In subsequent months, your ESRD Network will distribute to you additional data feedback reports. You may also find these reports on the Internet at www.hcfa.gov/medicare/hsqb/hsqb6c/htm. Please take the time to review these reports as you receive them and provide us with feedback as to the usefulness of the reports and ways you would like to see the clinical data displayed.

In the future, the ESRD Networks in collaboration with ESRD facilities will continue to assess the prevalence of the ESRD Core Indicators in adult, incenter hemodialysis and peritoneal dialysis patients in the U.S. The purpose of this effort will be to assess improvement in care to these patients and encourage further improvements. The ultimate goal for this project is to improve care for these patients.

#### VI. HEMODIALYSIS PATIENTS

#### A. SYNOPSIS

 Purpose of Project: The ultimate purpose of the ESRD Core Indicators Project is to assist providers of ESRD services to improve care provided to ESRD patients. The immediate purposes of the 1997 project are:

To compare the prevalence of important clinical characteristics of adult (aged  $\geq$  18 years), in-center hemodialysis patients in the U.S. in Oct-Dec 1996 to the prevalence of those characteristics in Oct-Dec 1993, Oct-Dec 1994, and Oct-Dec 1995; AND, To identify opportunities to improve care for those patients.

• Method Used: A random sample of adult, in-center hemodialysis patients who were alive on December 31, 1996 was selected (sample size 7292).

ESRD facilities, with assistance from ESRD Networks, submitted to HCFA clinical information about these patients for the time period October, November, December, 1996.

• Initial Findings: Data were submitted for 6858 (94%) of the patients in the sample. Highlights from the initial findings include:

#### IMPROVEMENT OCCURRED

- 68% of the sampled patients were receiving dialysis with urea reduction ratio (URR)  $\geq$  65%; there was a 9 percentage point increase in patients receiving dialysis with URR  $\geq$  65% from late 1995 to late 1996 (FIGURE 2).
- 63% of African-Americans and 70% of Caucasians were receiving dialysis with URR ≥ 65%, in Oct-Dec 1996; this was a 9 percentage point increase for African-American patients and a 7 percentage point increase for Caucasian patients from late 1995 to 1996 (FIGURE 14).
- 72% of patients had a mean hematocrit > 30% in the last quarter of 1996 compared to 63% of the patients in the last quarter of 1995, a 9 percentage point increase from late 1995 to late 1996 (FIGURE 4).
- 4% of African-Americans and 2% of Caucasians were severely anemic (severe anemia for this report is defined as hematocrit < 25%) in Oct-Dec 1996 compared to 6% and 3% respectively, in Oct-Dec 1995. (FIGURE 24)
- There exists variation among Networks for percentages of patients receiving hemodialysis with a delivered URR  $\geq$  65% (range from 56% 80%) (TABLE 6a) and for percentages of patients with hematocrit levels > 30% (range from 65% 85%). (TABLE 10b)

#### LITTLE OR NO CHANGE

- Approximately 1 in 5 patients had serum albumin levels < 3.5 gm/dL, reflecting little change from previous study years.
- Next Steps: Network and HCFA staff will work with ESRD facility staff to carry out intervention activities to document further improved care for ESRD patients in 1998 and 1999.

#### B. ADEQUACY OF DIALYSIS

This section and sections C and D will consist of two parts: (1) Core Indicators results from 18 ESRD Network areas for October-December 1996; and (2) a comparison of Core Indicators results for October-December 1996 and previous study period(s).

#### 1. October-December 1996

The mean URR for the national sample of adult, in-center hemodialysis patients in the last quarter of 1996 was 66.8%. The distribution of URR values for these patients is shown in Figure 7. The mean URR and Kt/V values, and the percent of patients with URR  $\geq$  65% or Kt/V  $\geq$  1.2 for gender, race, age, and diagnosis are shown in Table 5.

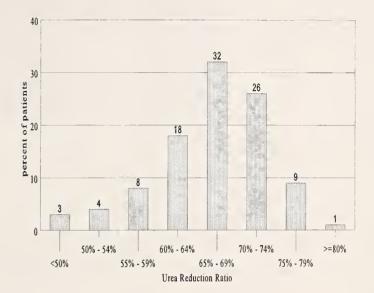
The Renal Physicians Association, an NIH Consensus Development Conference Panel, and the NKF DOQI Clinical Practice Guidelines for Hemodialysis Adequacy have recommended that adequate hemodialysis should result in a Kt/V > 1.2, approximately equivalent to URR > 65%. (1,11,12) The percent of patients who received adequate hemodialysis by this definition in the last quarter of 1996 was 68% (TABLE 5). The percent of patients receiving hemodialysis with a URR > 65% was higher for women than for men, higher for Caucasians than for African-Americans, and higher for patients > 65 years of age than for those 18-44 and 45-64 years of age. (FIGURES 8,9). The percent of ESRD patients with a diagnosis of Hypertension, Glomerulonephritis, Other/unknown who received hemodialysis with a URR > 65% is shown in Figure 10.

The percent of patients who received adequate hemodialysis varied substantially from one geographic region to another. Table 6a shows the percent of patients who received hemodialysis with a URR  $\geq$  65% by race and gender in each Network area: the percent ranged from 56% to 80% (FIGURES 11,12). Similarly, Table 6b shows the percent of patients by Network with a delivered Kt/V  $\geq$  1.2; the percent ranged from 61% to 85%.

The mean time spent on dialysis per dialysis session was 208 minutes. The mean time spent on dialysis was somewhat longer for men than women (215 minutes vs. 200 minutes), and African-

Americans than Caucasians (212 minutes vs. 206 minutes) (TABLE 7). The mean time spent on dialysis did not differ substantially for patients by either URR or Kt/V category (TABLE 7). The distribution of the mean time on dialysis for these patients is shown in Figure 13.

FIGURE 7: Distribution of mean URR values for adult (aged ≥18 years), in-center hemodialysis patients, October-December 1996. 1997 ESRD Core Indicators Project.



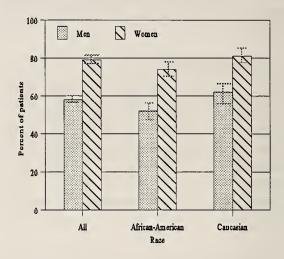
#### Note Regarding Race:

In this report several tables describe important clinical characteristics of adult in-center hemodialysis and peritoneal dialysis patients for the following race groups: American Indian/ Alaska Native, Asian/Pacific Islander, African-American, Caucasian, and other/unknown. In the figures where these clinical characteristics are compared by race group, however, comparisons are limited to Caucasian vs. African-American. The reason for this is sample size. Because of small sample size (Table 2) the 95% confidence intervals (see note regarding statistics) for estimates for Asian/Pacific Islander, American Indian/Alaska Native, or other/unknown race groups are very broad. On the other hand, the sample size for Caucasian and African-American patients was large enough to provide very stable estimates, i.e., the 95% confidence intervals are narrow.

TABLE 5: Mean URR, mean Kt/V, and percent of adult (aged  $\geq$  18 years), in-center hemodialysis patients with URR  $\geq$  65%, mean Kt/V, and Kt/V  $\geq$  1.2, October-December 1996, by patient characteristics. 1997 ESRD Core Indicators Project.

Patient Characteristic	Mean URR (%)	URR ≥ 65%	Mean Kt/V	Kt/V ≥ 1.2
TOTAL	67	68	1.34	74
GENDER				
Men	65	58	1.29	66
Women	69	79	1.40	82
RACE				
American Indian/ Alaska Native	71	80	1.49	83
Asian/Pacific Islander	69	72	1.41	81
African-American	66	63	1.32	70
Caucasian	67	70	1.35	75
Other/Unknown	68	75	1.40	79
AGE GROUP-yrs				
18-44	66	64	1.34	71
45-64	66	65	1.32	72
65+	68	72	1.36	76
DIAGNOSIS				
Diabetes mellitus	67	68	1.34	74
Hypertension	67	65	1.34	72
Glomerulonephritis	67	69	1.35	74
Other/Unknown	67	71	1.36	74

FiIGURE 8: Percent of adult (aged  $\ge$  18 years), in-center hemodialysis patients with mean URR  $\ge$  65%, October-December 1996, by race and gender. 1997 ESRD Core Indicators Project.



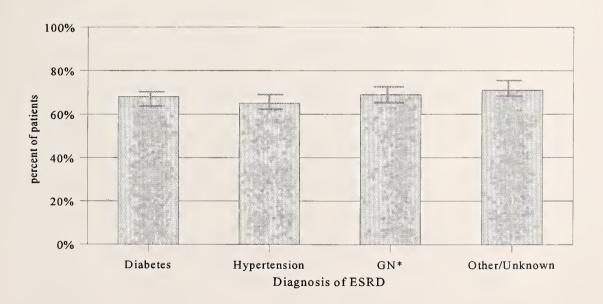
#### Note Regarding Statistics:

Readers may be interested to know if some of the patterns of clinical characteristics in this report show statistically significant differences, e.g., comparisons among age groups, racial groups, or geographic areas. To assist readers we have included 95% confidence interval brackets (I) on selected bar charts. If the upper limit of one group's bracket does not overlap with the lower limit of another group's bracket, then the difference between the two groups is statistically significant. In Figure 8, for example, the percent of all women receiving adequate dialysis is statistically significantly higher than the percent of all men receiving adequate dialysis. contrast, in Figure 10, the difference between the percent of patients who received adequate dialysis, diagnosis of hypertension glomerulonephritis is not statistically significant.

FIGURE 9: Percent of adult (aged ≥18 years), in-center hemodialysis patients receiving dialysis with a mean URR ≥ 65%, October-December 1996, by age group. 1997 ESRD Core Indicators Project.



FIGURE 10: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients receiving dialysis with a mean URR ≥ 65% October-December 1996, by diagnosis. 1997 ESRD Core Indicators Project.



<sup>\*</sup> Glomerulonephritis

TABLE 6a: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients receiving dialysis with a mean URR ≥ 65% in October-December 1996, by patient characteristics and Network. 1997 ESRD Core Indicators Project.

					•		•		NETWORK	ORK		•						
CHARACTERISTIC	-	2	3	4	so.	9	7	∞	6	10	11	12	13	14	15	91	17	18
ALL	77	59	7.1	69	57	72	99	71	69	56	64	74	59	74	08	89	70	71
RACE																		
African-American	77	51	73	19	55	73	61	89	64	54	52	69	58	89	72	64	65	09
Caucasian	77	62	74	70	62	70	70	75	70	58	69	92	58	77	78	89	64	75
MEN																		
African-American	73	43	64	54	47	19	49	61	53	47	39	64	42	55	50	45	54	40
Caucasian	69	53	89	62	51	54	09	69	61	49	63	69	46	29	72	63	56	64
WOMEN																		
African-American	08	61	83	79	64	82	75	75	75	63	99	74	74	82	06	88	79	82
Caucasian	68	75	82	81	74	98	87	82	82	69	78	84	08	98	98	75	72	68

TABLE 6b: Percent of adult (aged  $\ge 18$  years), in-center hemodialysis patients receiving dialysis with a mean  $Kt/V \ge 1.2$  in October-December 1996, by patient characteristics and Network. 1997 ESRD Core Indicators Project.

									NETWORK	ORK	•	•						
PATIENT CHARACTERISTIC	-	7	3	4	v	9	7	∞	6	01	=	12	13	14	15	91	17	18
ALL	82	64	92	72	19	78	73	78	72	63	89	78	71	82	85	74	77	9/
RACE																		
African-American	87	61	77	69	61	62	71	77	64	59	58	92	72	77	80	71	72	89
Caucasian		63	78	74	62	92	92	77	77	89	71	79	19	83	82	73	70	78
MEN																		
African-American	88	57	70	54	58	69	63	75	54	54	48	77	63	99	62	09	61	54
Caucasian	74	53	74	89	51	65	69	72	70	61	67	73	09	92	80	69	63	89
WOMEN																		
African-American	87	65	85	82	65	98	08	79	74	64	89	92	80	68	95	87	85	85
Caucasian	16	78	83	82	74	68	88	84	83	92	78	98	80	06	98	79	77	91

FIGURE 11. Percent of adult (aged ≥ 18 years), in-center hemodialysis patients receiving dialysis with a mean URR ≥ 65%, October - December 1996, by Network. 1997 ESRD Core Indicators Project.

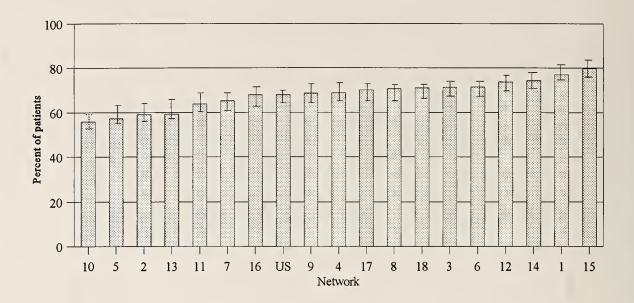


FIGURE 12: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients receiving dialysis with a mean URR ≥ 65%, October-December, 1996, by Network. 1997 ESRD Core Indicators Project.

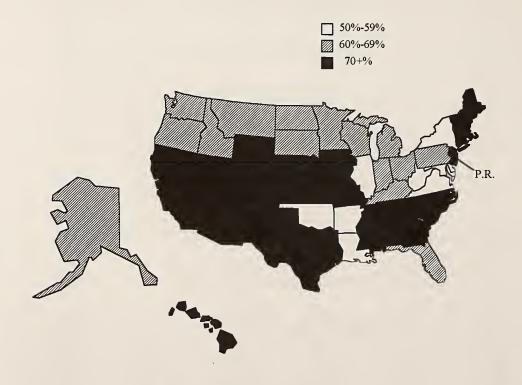
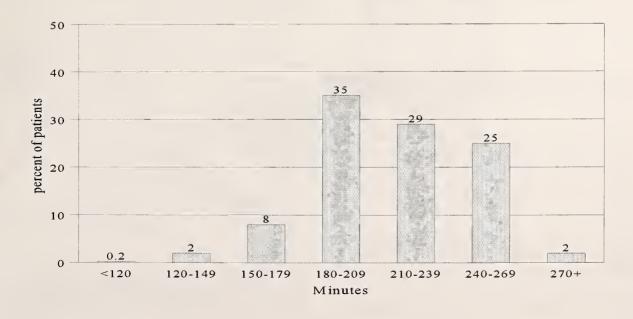


TABLE 7: Mean time on dialysis for adult (aged ≥18 years), in-center hemodialysis patients in the U.S., October-December 1996, by patient characteristics. 1997 ESRD Core Indicators Project.

PATIENT CHARACTERISTIC	Mean time on dialysis		Mean time per dialysis session (minutes) $URR < 65\%  URR \ge 65\%  Kt/V < 1.2  Kt/V \ge 1.$								
	(minutes)	URR < 65%	URR ≥ 65%	Kt/V < 1.2	$Kt/V \ge 1.2$						
TOTAL	208	208	208	205	209						
GENDER											
Men	215	212	217	209	218						
Women	200	199	200	197	201						
RACE											
American Indian/Alaska Native	206	211	208	205	210						
Asian/Pacific Islander	193	198	191	200	191						
African-American	212	213	212	209	214						
Caucasian	206	204	206	202	207						
Other/Unknown	204	202	205	201	204						
AGE GROUP (years)											
18-44	213	214	213	212	214						
45-64	213	213	213	210	214						
65+	202	200	203	197	203						
DIAGNOSIS											
Diabetes mellitus	211	209	211	207	212						
Hypertension	206	208	206	204	207						
Glomerulonephritis	208	208	208	205	209						
Other/unknown	205	206	205	204	206						

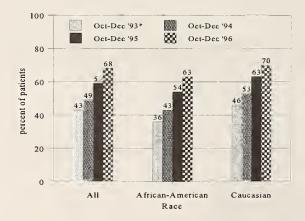
FIGURE 13: Distribution of time on dialysis (minutes) for adult (aged ≥ 18 years), in-center hemodialysis patients in the U.S., October-December 1996. 1997 ESRD Core Indicators Project.



# 2. October-December 1996 compared to previous study years

The average URR in October-December 1996 was 67%, an increase from previous study years. The proportion of patients receiving dialysis with a URR > 65% increased significantly from 59% in late 1995 to 68% in late 1996 (FIGURE 2). This significant improvement occurred for both Caucasian and African-American patients (FIGURE 14). Nationally, this improvement means that approximately 15,000 patients were receiving hemodialysis with a URR > 65% in late 1996 who would not have received this level of dialysis had they been dialyzing one year earlier (FIGURE 14).

FIGURE 14: Percent of adult (aged  $\geq$ 18 years), incenter hemodialysis patients with mean URR  $\geq$ 65% in October-December, 1996 compared to October-December 1993\*, 1994, and 1995, by race. 1997 ESRD Core Indicators Project.



\* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all Network areas participated in subsequent years.

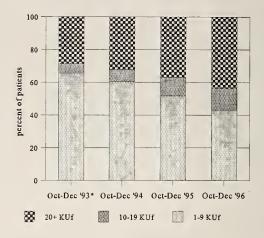
Figure 15 shows the percent of adult, in-center hemodialysis patients receiving hemodialysis with a URR  $\geq$  65% in October-December, 1996 by dialyzer KUf value compared to October-December, 1993, 1994, and 1995.

Figure 16 shows a trend for slightly increasing dialysis session lengths from late 1993 to late 1996.

From late 1995 to late 1996 there was an increase

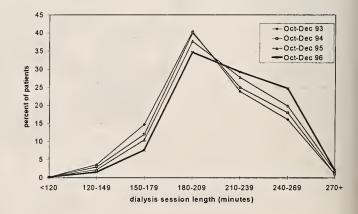
in the proportion of patients receiving dialysis with a URR  $\geq$  65% in 17 of the 18 Network areas (FIGURE 17), and in ten of the Network areas the increase was statistically significant (FIGURE 18).

FIGURE 15: Percent of adult (aged  $\geq$  18 years), incenter hemodialysis patients with mean URR  $\geq$  65% in October-December '96, by dialyzer KUf value, compared to October-December '93\*, '94, and '95. 1997 ESRD Core Indicators Project.



\* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all Network areas participated in subsequent years.

FIGURE 16: Distribution of dialysis session length (minutes) in October-December 1996 compared to October-December 1993\*, 1994, and 1995. 1997 ESRD Core Indicators Project.



\* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all Network areas participated in subsequent years.

FIGURE 17: Percent of adult (≥ 18 years), in-center hemodialysis patients with mean URR ≥ 65%, October-December 1996 compared to October-December 1993\*, 1994, and 1995, by Network. 1997 ESRD Core Indicators Project.

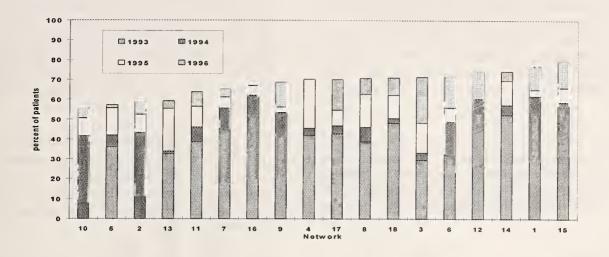
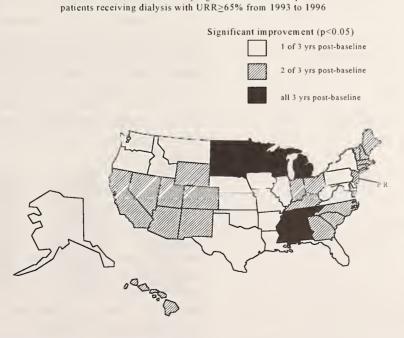


FIGURE 18: ESRD Networks areas with statistically significant improvement in the percent of adult (aged  $\geq$  18 years), in-center hemodialysis patients with mean URR  $\geq$  65%, October-December 1996 compared to October-December 1993\*, 1994 and 1995. 1997 ESRD Core Indicators Project. (Baseline = Oct-Dec '93)

Network areas with statistically significant increase in percent of



<sup>\*</sup> Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all Network areas participated in subsequent years.

Table 8 depicts the Odds Ratio (95% CI) for experiencing hemodialysis with a delivered Kt/V <1.2 by several patient and practice characteristics. The logistic regression analyses were conducted separately for each characteristic examined; the referent category is noted in each case. For example: a male has a 2.2 greater chance of experiencing a delivered Kt/V of < 1.2 than a female (without controlling for any other variables).

\_\_\_\_\_\_

TABLE 8: Independent logistic regression analyses by selected patient and practice characteristics to predict Odds Ratio (95% CI) for hemodialysis with Kt/V < 1.2. 1997 ESRD Core Indicators Project.

Characteristic	Odds Ratio (95% CI)
Gender Male Female (referent)	2.2 (2.0, 2.5)
Race African-American Caucasian (referent)	1.3 (1.1, 1.4)
Age group (years) 18-44 45+ (referent)	1.1 (0.9, 1.3)
Diabetes mellitus status DM+ DM- (referent)	0.98 (0.87, 1.1)
Body weight (in kg) Highest quartile Lower 75% (referent)	2.2 (2.0, 2.5)
Years on dialysis < 1 yr 1+ yrs (referent)	2.4 (2.1, 2.7)
Dialysis session length (r < 210 210+ (referent)	ninutes) 1.3 (1.2, 1.5)
Dialyzer KUf 1-19 20+ (referent)	1.3 (1.2, 1.5)

#### C. ANEMIA MANAGEMENT

#### 1. October-December 1996

The distribution of hematocrit values for African-American and Caucasian patients is shown in Figure 19. The mean hematocrit for adult, in-center hemodialysis patients in the U.S. in the last quarter of 1996 was 32.7%. The mean hematocrit values for gender, race, age, and diagnosis are shown in Table 9.

The percent of patients with severe anemia (hematocrit < 25%) was 3%. The prevalence of severe anemia was higher in patients 18-44 years of age compared to older patients and, as reported previously (19), higher in African-Americans than Caucasians (TABLE 9).

While the mean hematocrit varied very little from one geographic area to another (range 32.0% to 33.9%), the percent of patients with hematocrit values between 33%-36% and the percent of patients with hematocrit values > 30% varied markedly.

Tables 10a and 10b show the percent of patients by race and age group in each Network with hematocrit values between 33%-36%, the target range specified by the NKF DOQI Clinical Practice Guideline for the Treatment of Anemia of Chronic Renal Failure (14), and the percent of patients with hematocrit values >30%, by Network, respectively. The percent of all patients with hematocrit values between 33% - 36% ranged from 37% to 51% (TABLE 10a, FIGURE 20). The percent of all patients with hematocrit values > 30% ranged from 65% to 85% (TABLE 10b, FIGURES 21,22).

Because patients could receive Epoetin during one Project month but not during another we were not able to correlate Epoetin use with the mean hematocrit values. Instead, we assessed Epoetin use at the time of each of the 19,538 hematocrit determinations reported in this Project. Overall, Epoetin was being used 95% of the time when a hematocrit value was determined. (TABLE 11) Recombinant human erythropoietin was being used 95% of the time when the hematocrit values were < 25%, 97% of the time when the hematocrit ranged from 25-30% and from 31-35%, and 83%

of the time when the hematocrit values were ≥ 36% (TABLE 11). The use of Epoetin and the average dose (units per kg) at the time of hematocrit determinations for gender, race, age, and diagnosis groups are also shown in Table 11.

FIGURE 19: Distribution of mean hematocrit values for adult (aged ≥18 years), in-center hemodialysis patients in the U.S.,October-December 1996. by race. 1997 ESRD Core Indicators Project.

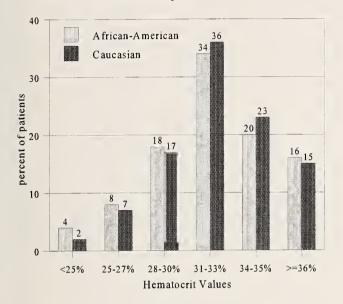
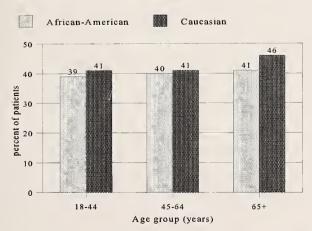


FIGURE 20: Percent of adult (aged  $\geq$  18 years), incenter hemodialysis patients with mean hematocrit levels between 33%-36%, October-December 1996, by age and race. 1997 ESRD Core Indicators Project.



During this study period, data were collected for the first time on additional measures useful for anemia management. The national average percent transferrin saturation for the patients in the sample was 27.4 and ranged from 24.7 to 29.4 among the eighteen Network areas (TABLE 12). Table 12 also provides the percent of patients with transferrin saturation values ≥20% nationally (63%) and by Network area, ranging from 49% to 75%.

The national average ferritin level for the patients in the sample was 377 ng/ml and ranged from 320 to 426 ng/ml among the eighteen Network areas. The percent of patients with ferritin levels  $\geq$  100 ng/ml nationally was 73%, ranging from 60% to 80% (TABLE 12).

The percent of patients with intravenous (IV) iron prescribed nationally was 39%, ranging from 29% to 52% among the eighteen Network areas (TABLE 12).

Ninety-three percent of patients in this sample received Epoetin by the IV route; 7% received Epoetin subcutaneously, the route recommended by the NKF-DOQI clinical practice guidelines for the treatment of anemia. (14)

TABLE 9: Hematocrit values for adult (aged ≥18 years), in-center hemodialysis patients in the U.S., October-December 1996, by patient characteristics. 1997 ESRD Core Indicators Project.

	Hematocrit	hematocrit	ematocrit values			
Patient Characteristic	mean	< 25%	25-30%	31-35%	≥ 36%	
TOTAL	32.7	3	25	57	15	
GENDER						
Men	33.0	3	24	56	18	
Women	32.5	3	26	58	13	
RACE			<u> </u>			
American Indian/Alaska Native	32.9	4	22	57	17	
Asian/Pacific Islander	33.6	0	18	63	19	
African-American	32.6	4	26	54	16	
Caucasian	32.8	2	24	59	15	
Other/Unknown	32.8	2	24	58	15	
AGE GROUP (years)			]   		1 	
18-44	32.4	5	28	51	16	
45-64	32.7	3	26	56	16	
65+	32.9	2	23	61	14	
DIAGNOSIS			]   	 		
Diabetes mellitus	32.7	2	26	57	15	
Hypertension	32.7	3	24	60	14	
Glomerulonephritis	32.7	3	26	54	17	
Other/Unknown	32.8	4	24	55	17	

<sup>\*</sup>note: percents may not add up to 100% due to rounding

TABLE 10a: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with hematocrit values between 33-36%, October-December 1996, by age, race, and Network. 1997 ESRD Core Indicators Project.

					•				NETWORK	ORK								
Patient Characteristic	1	2	3	4	S	9	7	∞	6	10	=	12	13	4	15	16	17	18
ALL	40	40	42	44	43	43	46	4	44	40	38	40	37	39	40	51	46	47
RACE																		
African-American	40	41	42	47	38	43	39	40	35	36	34	46	39	34	37	42	48	45
Caucasian	41	38	44	44	54	43	51	43	47	42	42	35	34	43	40	52	49	46
AGE GROUP (years)																		
18-44																		
African-American	43	44	23	46	47	46	33	33	24	35	14	32	41	14	0	39	43	39
Caucasian	46	39	22	41	50	44	30	36	39	46	37	38	59	46	33	45	46	41
45-64																-3-, 1 /		
African-American	31	39	52	47	36	43	44	39	35	36	38	49	38	59	38	38	48	37
Caucasian	36	44	46	46	54	36	47	40	47	35	37	24	20	42	37	45	47	42
65+																		
African-American	48	43	41	47	35	40	38	44	39	37	26	58	39	37	54	50	52	09
Caucasian	40	35	46	44	54	47	55	47	48	45	45	38	43	42	45	09	51	51
											_	_		_	_	_		

TABLE 10b: Percent of adult (aged ≥18 years), in-center hemodialysis patients with hematocrit values > 30%, October-December 1996, by age, race, and Network. 1997 ESRD Core Indicators Project.

	18	62		74	78			99	9/		73	77		92	79
	17	78			79			7.1	73		8	78		85	83
	91	85		83	84			77	79		8	8		92	68
	15	74		89	74			57	7.1		7.1	29		69	79
	14	69		99	72			89	62		89	69		09	78
	13	65		99	64			29	52		64	99		89	71
	12	72		74	71			55	99		73	65		87	74
	=	69		64	71			70	63		89	63		99	77
NETWORK	10	89		99	69			99	75		29	58		70	74
NETV	6	72		64	75			48	72		58	75		92	92
	∞	89		65	73			53	62		29	70		70	74
	7	71		64	92			51	70		89	11		69	92
	9	73		74	69			7.7	72		75	89		72	89
	S	71		69	92			99	<i>L</i> 9		72	80		89	92
	4	92		77	77			85	78		72	80		79	74
	3	70		92	69			58	72		83	29		78	70
	2	70		69	73			72	58		69	75		64	92
	_	79		87	77			98	82		85	61		06	82
	Patient Characteristic	ALL	RACE	African-American	Caucasian	AGE GROUP (years)	18-44	African-American	Caucasian	45-64	African-American	Caucasian	+59	African-American	Caucasian

FIGURE 21: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with mean hematocrit > 30%, October-December 1996, by Network. 1997 ESRD Core Indicators Project.

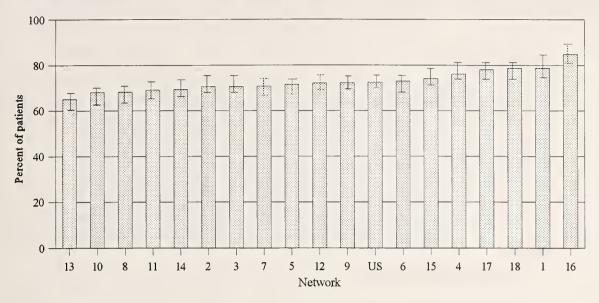


FIGURE 22: Percent of adult (aged ≥18 years), in-center hemodialysis patients with mean hematocrit > 30%, October-December 1996, by Network. 1997 ESRD Core Indicators Project.

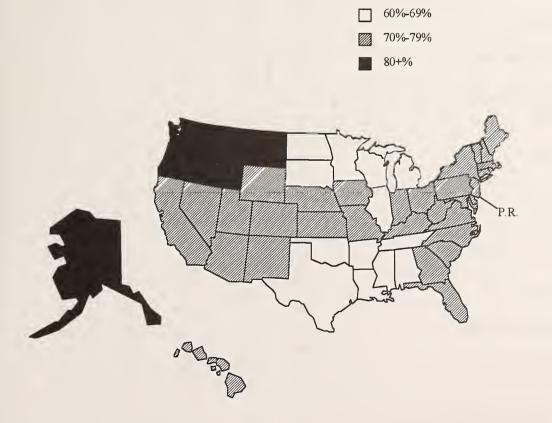


TABLE 11: Percent of adult (aged ≥18 years), in-center hemodialysis patients in the U.S. receiving Epoetin at time hematocrit was drawn and the average Epoetin dose, October-December 1996, by patient characteristics. 1997 ESRD Core Indicators Project

		!			
Patient Characteristic			Hematocr	it values	
	Overall %	<25% (dose*)	25-30% (dose*)	31-35% (dose*)	≥36% (dose*)
TOTAL	95	95	97	97	83
	(68)	(92)	(78)	(63)	(62)
GENDER					
Men	93	95	96	97	77
	(63)	(89)	(74)	(59)	(55)
Women	97	96	97	98	92
	(72)	(96)	(81)	(68)	(70)
RACE					
American Indian/Alaska Native	99 (75)	100 (113)	100 (89)	100 (67)	92 (73)
Asian/Pacific Islander	98 (69)	 (41)	100 (75)	100 (68)	87 (65)
African-American	95 (68)	95 (99)	96 (75)	97 (62)	82 (64)
Caucasian	95 (67)	96 (91)	97 (78)	97 (64)	84 (58)
Other/Unknown	95	95	98	97	83
	(70)	(62)	(85)	(62)	(73)
AGE GROUP (years)			i		İ
18-44	93	97	98	97	75
	(74)	(100)	(83)	(68)	(65)
45-64	94	92	96	97	78
	(66)	(86)	(76)	(61)	(59)
65+	96	98	97	98	91
	(67)	(93)	(77)	(63)	(63)
DIAGNOSIS				İ	
Diabetes mellitus	95	92	97	97	86
	(65)	(84)	(77)	(60)	(59)
Hypertension	96	99	97	98	84
	(67)	(90)	(72)	(65)	(64)
Glomerulonephritis	95	95	97	96	85
	(69)	(90)	(81)	(63)	(59)
Other/Unknown	93	96	96	97	76
	(72)	(106)	(83)	(67)	(67)

<sup>\*</sup>dose=units per Kg

TABLE 12: Regional variation for various anemia management measures for adult (aged  $\geq 18$  years), in-center hemodialysis patients, October-December 1996, national and by Network. 1997 ESRD Core Indicators Project.

	Sn	27.4	63	377	73	39
	18	27.8	99	401	8	33
	17	27.1	67	426	79	31
	16	27.6	49	329	63	46
	15	29.4	75	339	72	52
	14	27.1	71	424	80	34
	13	29.1	09	366	78	52
	12	26.1	55	393	69	36
	11	26.9	62	345	70	36
ORK	10	28.8	92	356	70	34
NETWORK	6	26.8	58	353	72	46
	8	26.4	58	332	17	34
	7	27.3	62	386	76	43
	9	29.0	62	425	74	43
	5	28.0	62	384	70	37
	4	28.5	99	412	75	47
_	33	27.0	63	324	11	35
	2	24.7	53	320	09	59
	-	25.9	64	392	75	36
	Anemia Management Measure:	Average Percent Transferrin Saturation	Percent of patients with Percent Transferrin Saturation $\geq 20\%$	Average Ferritin level (ng/ml)	Percent of patients with Ferritin level >100 ng/ml	Percent of patients with IV Iron Prescribed

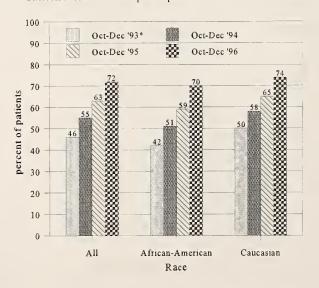
## 2. October-December 1996 compared to previous study periods.

The average hematocrit from October-December 1995 to October-December 1996 increased from 31.9% to 32.7%, and the percentage of patients with a mean hematocrit > 30% increased significantly from 63% to 72% (FIGURE 23). This significant improvement occurred towards a goal of the National Anemia Cooperative Project for both Caucasian and African-American patients.

In addition to the marked improvement in the percentage of patients with hematocrit >30%, there was also a decrease in the percentage of patients with severe anemia (hematocrit < 25%). In October-December 1995, 6% of African-American patients and 3% of Caucasian patients had severe anemia, while in October-December 1996, 4% of African-American patients and 2% of Caucasian patients had severe anemia. (FIGURE 24)

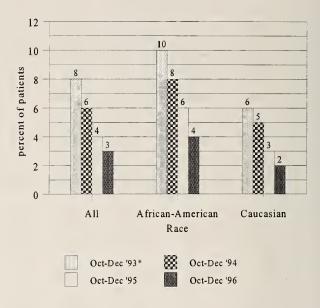
FIGURE 23: Percent of adult (aged ≥18 years), incenter hemodialysis patients with mean hematocrit > 30%, October-December 1996 compared to October-December 1993\*, 1994, and 1995, by race. 1997 ESRD Core Indicators Project.

<sup>\*</sup> Sixteen Network areas participated in the first ESRD Core



Indicators assessment (Oct-Dec '93); all Network areas participated in subsequent years.

FIGURE 24: Percent of adult (aged ≥ 18 years), incenter hemodialysis patients with severe anemia (hematocrit < 25%), by race, October-December 1996 compared to October-December 1993\*, 1994, and 1995. 1997 ESRD Core Indicators Project.

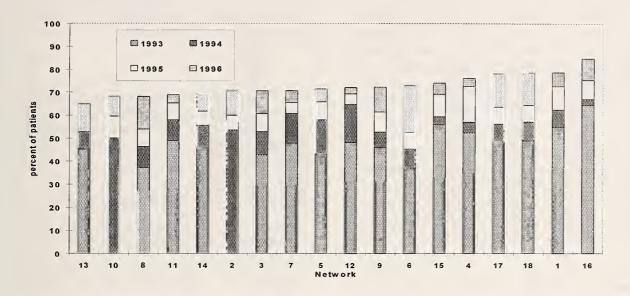


\*Sixteen Network areas participated in the first ESRD Core Indicators assessment(Oct-Dec 1993); all Network areas participated in subsequent years.

From late 1995 to late 1996 there was an increase in the proportion of patients with hematocrit > 30% in all 18 Network areas, and in 11 of these areas the increase was statistically significant (FIGURE 25).

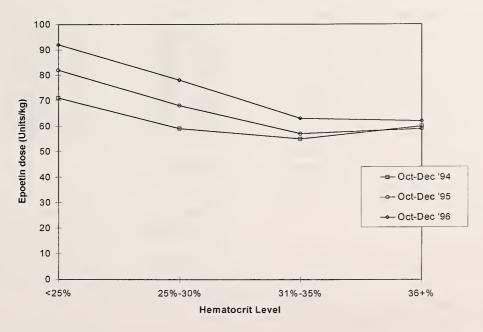
Figure 26 depicts a trend in Epoetin dosing from late 1994 to late 1996, with an increasing mean Epoetin dose (units/kg) for patients in most hematocrit categories each successive study year.

FIGURE 25: Percent of adult (≥ 18 years), in-center hemodialysis patients with mean hematocrit > 30% in October-December 1996 compared to October-December 1993\*, 1994, and 1995, by Network. 1997 ESRD Core Indicators Project.



<sup>\*</sup>Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all 18 Network areas participated in subsequent years.

FIGURE 26: Mean Epoetin dose (units/kg) for adult (aged ≥ 18 years), in-center hemodialysis patients, by hematocrit category, October-December 1996 compared to October-December 1994, and 1995. 1997 ESRD Core Indicators Project.



#### D. SERUM ALBUMIN

## 1. October-December 1996

The two commonly used laboratory methods for determining serum albumin levels, bromcresol green (BCG) and bromcresol purple (BCP), have been reported to yield systematically different results. (15) Therefore, we assessed the serum albumin values reported for these two methods separately. As expected, the values determined by the BCP method were systematically lower than those determined by the BCG method (TABLE 13).

The mean serum albumin value for patients whose value was determined by the BCG method (N=5,681) was 3.8 gm/dL, and by the BCP method (N=1,107) was 3.6 gm/dL. The mean serum albumin values for gender, race, age, and diagnosis groups are shown in Table 13.

Serum albumin values <3.5 gm/dL by the BCG method were defined as an indicator of inadequate serum albumin level. (20) Since the percent of serum albumin values <3.2 gm/dL by the BCP method (16%) was nearly the same as the percent of serum albumin values <3.5 gm/dL by the BCG method (19%), we also defined a BCP result <3.2 gm/dL as an indicator of inadequate serum albumin level. Figure 27 displays the distribution of serum albumin values by laboratory method.

Table 13 also shows the percent of patients by gender, race, age, and diagnosis groups with mean serum albumin values  $\geq 3.5$  gm/dL by the BCG method or  $\geq 3.2$  gm/dL by the BCP method. The percent of patients with mean serum albumin values  $\geq 3.5$  gm/dL by the BCG or  $\geq 3.2$  gm/dL by the BCP method tended to be higher for African-Americans than for Caucasians, and for men than for women (FIGURE 28). The percent of patients in each Network area with mean serum albumin values  $\geq 3.5$  gm/dL by BCG or  $\geq 3.2$  gm/dL by BCP methods is shown in Table 14; the percent ranged from 76% to 86%.

## 2. October-December 1996 compared to previous study periods.

There was no clinically important change or improvement in the proportion of adult, in-center

hemodialysis patients with sub-optimal serum albumin levels from October-December 1996 compared to previous study periods.

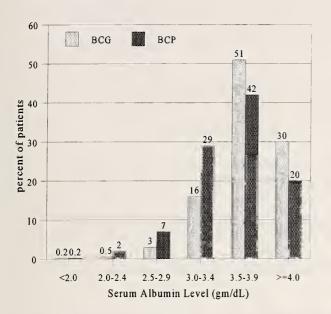
Figure 29 shows the percent of patients with mean serum albumin values  $\geq 3.5 \text{gm/dL}$  by the BCG method or  $\geq 3.2 \text{gm/dL}$  by the BCP method during October-December 1996 compared to October-December 1993, 1994 and 1995.

TABLE 13: Serum albumin values (gm/dL) for adult (aged ≥18 years), in-center hemodialysis patients in the U.S., Oct-Dec 1996 by patient characteristics and by laboratory method\*. 1997 ESRD Core Indicators Project.

	BCG		ВС	CP CP
PATIENT CHARACTERISTIC	mean	% ≥ 3.5	mean	% ≥ 3.2
TOTAL	3.8	81	3.6	84
GENDER				
Men	3.8	84	3.7	87
Women	3.7	78	3.5	80
RACE				
American Indian/ Alaska Native	3.7	75	3.2	45
Asian/Pacific Islander	3.9	86	3.5	87
African-American	3.8	82	3.6	86
Caucasian	3.8	80	3.6	82
Other/Unknown	3.8	83	3.7	88
AGE GROUP (years)				
18-44	3.9	85	3.7	88
45-64	3.8	83	3.6	83
65+	3.7	78	3.5	83
DIAGNOSIS				
Diabetes mellitus	3.7	75	3.5	78
Hypertension	3.8	86	3.6	86
Glomerulonephritis	3.9	86	3.7	90
Other/Unknown	3.8	82	3.6	84

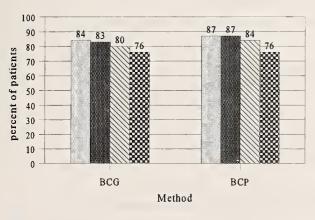
<sup>\*</sup>laboratory methods: BCG = bromcresol green; BCP = bromcresol purple

FIGURE 27: Distribution of serum albumin values for adult (aged≥18 years), in-center hemodialysis patients, October-December 1996, by laboratory method\*. 1997 ESRD Core Indicators Project.



<sup>\*</sup> BCG = Bromcresol green; BCP = Bromcresol purple

FIGURE 28: Percent of adult (aged  $\geq$ 18 years), incenter hemodialysis patients with mean serum albumin  $\geq$ 3.5 gm/dL (BCG method) or  $\geq$ 3.2 gm/dL (BCP method), October-December 1996, by race and gender. 1997 ESRD Core Indicators Project.



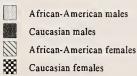
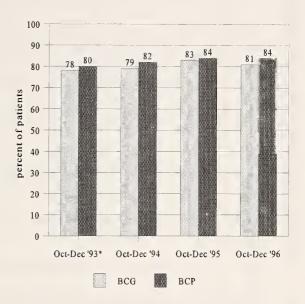


FIGURE 29: Percent of adult (aged  $\geq$  18 years), incenter hemodialysis patients with mean serum albumin  $\geq$  3.5 gm/dL (BCG method) or  $\geq$  3.2 gm/dL (BCP method), October-December 1996 compared to October-December 1993\*, 1994 and 1995. 1997 ESRD Core Indicators Project.



\* Sixteen Network areas participated in the first ESRD Core Indicators assessment (Oct-Dec '93); all 18 Network areas participated in subsequent years.

TABLE 14: Percent of adult (aged ≥ 18 years), in-center hemodialysis patients with serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), October-December 1996, by age, race, and Network. 1997 ESRD Core Indicators Project.

	18	82		84	81		83	98		93	83		9/	. 78	
_	17	83		84	84		62	80		06	98		78	83	
	16	9/		7.1	77		77	84		69	73		29	78	
	15	82		92	84		98	96		81	82		62	82	
	14	82		82	82		62	92		84	85		80	7.5	
	13	81		84	77		94	81		81	80		82	75	
	12	80		81	80		98	84		80	85		42	78	
	11	77		98	73		68	83		68	72		82	70	
NETWORK	10	92		74	78		73	87		81	79		29	74	
NETV	6	79		83	92		98	78		06	75		92	92	
_	∞	98		85	87		98	93		88	06		81	84	
-	7	84		80	98		80	80		98	83		73	88	
_	9	98		88	81		95	88		87	79		84	62	
	w	81		80	84		85	83		83	68		73	80	
	4	62		85	9/		26	70		79	74		83	78	
	e	83		78	84		73	78		83	91		9/	82	
	2	81		83	77		98	06		83	71		6/	77	
	1	82		77	83		71	82		84	85		72	82	·
	Patient Characteristic	ALL	RACE	African-American	Caucasian	AGE GROUP (years) 18-44	African-American	Caucasian	45-64	African-American	Caucasian	+59	African-American	Caucasian	

#### VII. PERITONEAL DIALYSIS PATIENTS

#### A. SYNOPSIS

 Purpose of Project: the ultimate purpose of the ESRD Core Indicators Project is to assist providers of ESRD services to improve care provided to ESRD patients. The immediate purposes of the 1997 project are:

To compare the prevalence of important clinical characteristics of adult (age ≥ 18 years), peritoneal dialysis patients in the U.S. in Nov-Dec 1996 & Jan-Apr 1997 to the prevalence of those characteristics in Nov-Dec 1995 & Jan-Apr 1996, and Nov-Dec 1994 & Jan-Apr 1995; AND, To identify opportunities to improve care for those patients.

• Method Used: A national random sample of adult, peritoneal dialysis patients who were alive on December 31, 1996 was selected (sample size 1375).

ESRD facilities, with assistance from ESRD Networks, submitted to HCFA clinical information about these patients for the time period Nov-Dec 1996 and Jan-Apr 1997.

• Initial Findings: Data were submitted for 1219 (89%) of the patients in the sample. Highlights from the initial findings include:

#### IMPROVEMENT OCCURRED

- Adequacy of dialysis was assessed for approximately 75% of the sampled patients during the 1997 study period, compared to 69% during the 1996 study period (Nov-Dec '95 & Jan-Apr '96).
- The mean hematocrit for the sampled patients during the 1997 study period was 33.8%, an increase from 33.1% during the 1996 study period. (FIGURE 6)
- There was a six percentage point increase in the percentage of peritoneal dialysis patients with mean hematocrit values > 30% from the 1996 study period (70%) to the 1997 study period (76%). (FIGURE 31)

#### OPPORTUNITIES TO IMPROVE

- 24% of the sampled peritoneal dialysis patients had mean hematocrit values < 31% in the 1997 study period.
- 45% of the sampled peritoneal dialysis patients had mean serum albumin values < 3.5 gm/dL (BCG method) or < 3.2 gm/dL (BCP method) in the 1997 study period.
- Approximately one in four of the sampled peritoneal dialysis patients had systolic blood pressure > 150 mmHg. (FIGURE 39)
- The adequacy of dialysis was not assessed during the 1997 study period for an estimated 25% of the sampled peritoneal dialysis patients.
- Next Steps: Network and HCFA staff will work with ESRD facility staff to carry out intervention activities to document further improved care for ESRD patients in 1998 and 1999.

## B. ADEQUACY OF DIALYSIS

## 1. November 1996-April 1997

Using values that were abstracted from medical records of peritoneal dialysis patients, it was possible to calculate at least one of the adequacy measures (weekly Kt/V or weekly creatinine clearance) for 793 (65%) of the 1219 patients during the 1997 study period. Of the 426 (35%) medical records with insufficient information to calculate an adequacy measure, 125 (29%) of these medical records had at least either one weekly Kt/V value (112 records) or one weekly creatinine clearance value (101) recorded during the 1997 study period.

More detailed information regarding weekly Kt/V and weekly creatinine clearance values will be provided in a supplemental report, which will be available on the Internet as well as from the Network offices.

## 2. November 1996-April 1997 compared to previous study years

The adequacy of dialysis was assessed at least once for approximately 75% of adult peritoneal dialysis patients during the 1997 six-month study period (Nov 1996 - Apr 1997), compared to only 66% during the 1995 study period, and 69% during the 1996 study period.

#### C. ANEMIA MANAGEMENT

## 1. November 1996-April 1997

The average hematocrit for adult peritoneal dialysis patients in the sample was 33.8%. The distribution of hematocrit values for African-American and Caucasian patients is shown in Figure 30. Overall, 39% of patients had hematocrit values between 33% and 36%, the range targeted by the NKF DOQI Clinical Practice Guideline for the Treatment of Anemia (TABLE 15a). (14) This Table also depicts the percent of patients with hematocrit values within this range by gender, race, age group and cause of ESRD.

The mean hematocrit values and the proportion of patients within different hematocrit categories for gender, race, age, and diagnosis are shown in Table 15b. The prevalence of severe anemia (hematocrit < 25%) was 1.4%. The prevalence of severe anemia was significantly higher in African Americans compared to Caucasians and for patients 18-44 years old compared to older patients (TABLE 15b).

Because patients could receive Epoetin during one Project two-month period but not during another, we were not able to correlate Epoetin use with the mean hematocrit values. Instead, we assessed Epoetin use at the time of each of the 3236 hematocrit determinations reported for this study period. Overall, Epoetin was being used 82% of the time when a hematocrit value was determined. Epoetin was used 94% of the time when the hematocrit values were < 25% and when the hematocrit ranged from 25-30%, 93% of the time when the hematocrit ranged from 31-35%, and 59% of the time when the hematocrit values were > 36%.

Iron use was assessed for the first time during this study period. Iron by either the oral or intravenous route was prescribed at least one of the two-month study periods for 77% of the patients in this sample, and throughout the six- month period for 59% of the patients. Of the patients prescribed iron, 94% were prescribed oral iron and 8% were prescribed intravenous iron (not mutually exclusive categories).

The average transferrin saturation for the patients in this sample was 28%, and 61% of patients had transferrin saturations  $\geq$  20% (TABLE 16). The average ferritin value for this population was 311 ng/ml, with 64% of patients having ferritin values  $\geq$ 100 ng/ml (TABLE 16).

# 2. November 1996-April 1997 compared to previous study periods

The average hematocrit increased from 32.5% during the 1995 study period to 33.1% during the 1996 study period to 33.8% during the 1997 study period (FIGURE 6). The percentage of peritoneal dialysis patients with mean hematocrit values >30% increased from 64% to 76% over the three study periods (FIGURE 31).

FIGURE 30: Distribution of hematocrit values for adult (aged ≥ 18 years), peritoneal dialysis patients, Nov '96-Apr '97, by race. 1997 ESRD Core Indicators Project.

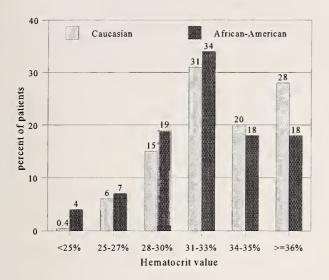


FIGURE 31: Percent of adult (aged≥18 years), peritoneal dialysis patients with mean hematocrit > 30%, Nov '96-Apr '97 compared to Nov '94-Apr '95 and Nov '95-Apr '96, by race. 1997 ESRD Core Indicators Project.

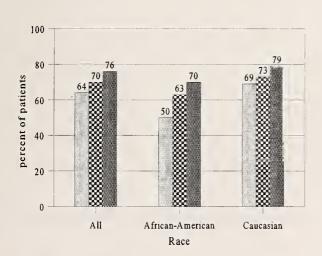




TABLE 15a: Percent of adult (aged ≥18 years), peritoneal dialysis patients with hematocrit values between 33%-36%, Nov '96-Apr '97. 1997 ESRD Core Indicators Project.

Patient Characteristic	% of patients with hematocrit values 33%-36%
TOTAL	38.7
GENDER Men	38.2
Women	39.3
RACE American Indian/ Alaska Native	0.0
Asian/Pacific Islander	47.1
African-American	37.0
Caucasian	38.5
Other/Unknown	46.8
AGE GROUP (years) 18-44	34.6
45-64	38.7
65+	42.9
DIAGNOSIS Diabetes Mellitus	41.3
Hypertension	36.3
Glomerulonephritis	41.2
Other/Unknown	35.6

Note: percents may not add up to 100% due to rounding

TABLE 15b: Hematocrit values for adult (aged ≥ 18 years), peritoneal dialysis patients, Nov '96-Apr '97, by patient characteristics. 1997 ESRD Core Indicators Project.

% of patients with hematocrit values Hematocrit <25% 25-27% 28-30% 31-33% 34-35% >36% Patient Characteristic Mean TOTAL 33.8 1.4 5.9 16.3 31.5 19.5 25.2 **GENDER** 8.0 14.8 Men 34.3 4.9 30.5 19.3 29.7 Women 33.2 2.1 7.0 17.9 32.6 19.8 20.5 **RACE** 0 American Indian/ 30.4 0 0 100 0 0 Alaska Native 0 17.6 33.8 5.9 23.5 29.4 23.5 Asian/Pacific Islander 19.0 32.8 4.2 6.7 33.5 18.3 18.3 African-American 34.1 0.4 5.8 14.9 31.0 19.9 28.0 Caucasian 33.6 2.2 4.5 16.9 32.6 21.3 22.5 Other/Unknown AGE GROUP (years) 33.0 3.8 10.1 15.8 29.1 19.9 21.2 18-44 0.7 5.1 18.5 30.9 18.7 26.0 45-64 33.9 13.1 34.9 20.5 27.8 65+ 34.2 0.3 3.4 **DIAGNOSIS** 33.8 1.0 4.2 16.7 31.9 19.6 26.7 Diabetes Mellitus 8.0 5.9 17.2 36.7 17.2 22.3 Hypertension 33.6 Glomerulonephritis 2.8 6.1 16.4 27.7 22.5 24.4 33.7 15.0 29.3 19.3 26.3 Other/Unknown 33.8 1.7 8.3

Note: percents may not add up to 100% due to rounding

TABLE 16: Various anemia management measures for adult (aged ≥ 18 years), peritoneal dialysis patients, Nov '96-Apr '97, by patient characteristics. 1997 ESRD Core Indicators Project.

Patient Characteristic	Mean Transferrin Saturation Level %	% Patients with Transferrin Saturation ≥ 20%	Mean Ferritin Level (ng/ml)	% Patients with Ferritin ≥ 100 ng/ml
TOTAL	28.1	61	311	64
GENDER Men	28.3	62	292	65
Women	28.0	60	331	63
RACE American Indian/Alaska Native	23.5	50	230	100
Asian/Pacific Islander	24.3	65	165	35
African-American	27.9	58	390	70
Caucasian	28.1	61	279	62
Other/Unknown	29.7	68	322	71
AGE GROUP (years) 18-44	28.7	64	320	62
45-64	27.6	58	284	63
65+	28.3	63	346	69
DIAGNOSIS Diabetes Mellitus	27.6	60	277	62
Hypertension	27.9	63	318	67
Glomerulonephritis	29.2	62	347	61
Other/Unknown	28.3	60	325	66

Note: percents may not add up to 100% due to rounding

The percent of adult (aged  $\geq$  18 years), peritoneal dialysis patients with severe anemia (hematocrit < 25%) decreased from 6% in the 1995 study period to 1.4% in the 1997 study period (FIGURE 32).

FIGURE 32. Percent of adult (aged  $\geq$  18 years), peritoneal dialysis patients with severe anemia (hematocrit < 25%), by race, Nov '96-Apr '97 compared to Nov '94-Apr '95, and Nov '95-Apr '96. 1997 ESRD Core Indicators Project.

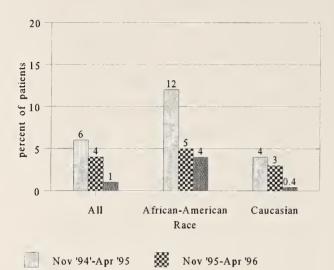
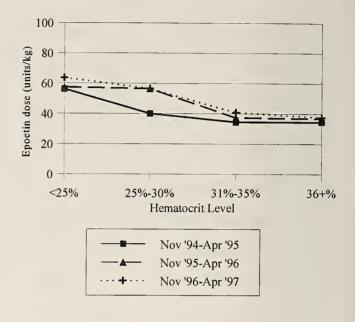


Figure 33 depicts a trend in Epoetin dosing from the 1995 study period to the 1997 study period, with an increasing mean Epoetin dose (units/kg) for patients in most hematocrit categories each successive study period.

Nov '96-Apr '97

FIGURE 33. Mean Epoetin dose (units/kg) by hematocrit category for adult (≥ 18 years), peritoneal dialysis patients from Nov '96-Apr '97 compared to Nov '94-Apr '95 and Nov '95-Apr '96. 1997 ESRD Core Indicators Project.



#### D. SERUM ALBUMIN

## 1. November 1996-April 1997

The mean serum albumin value for patients whose value was determined by the BCG method (n=952) was  $3.5\,\mathrm{gm/dL}$  and by the BCP method (n=203) was  $3.3\,\mathrm{gm/dL}$ . The mean serum albumin value by gender, race, age, and diagnosis groups and the percent of patients with mean serum albumin values  $\geq 3.5\,\mathrm{gm/dL}$  by the BCG or  $\geq 3.2\,\mathrm{gm/dL}$  by the BCP method are shown in Table 17. The percent of patients with mean serum albumin values  $\geq 3.5\,\mathrm{gm/dL}$  by the BCG or  $\geq 3.2\,\mathrm{gm/dL}$  by the BCP method tended to be higher for men compared to women and for patients 18-44 years compared to older patients (TABLE 17).

Figure 34 displays the distribution of serum albumin values by laboratory method. The percent of patients with mean serum albumin values  $\geq 3.5$  gm/dL by the BCG or  $\geq 3.2$  gm/dL by the BCP method tended to be higher for men than for women (TABLE 17, FIGURE 35).

## 2. November 1996-April 1997 compared to previous study years

There was no clinically important change or improvement in the proportion of adult peritoneal dialysis patients with serum albumin levels  $\geq$  3.5gm/dL by the BCG or  $\geq$  3.2gm/dL by the BCP method from the 1995 study period to the 1997

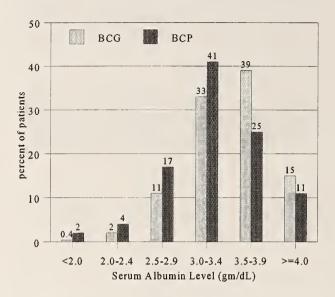
study period.

Figure 36 shows the percent of patients with mean serum albumin values  $\geq 3.5 \text{gm/dL}$  by the BCG or  $\geq 3.2 \text{gm/dL}$  by the BCP method during the 1997 study period compared to the 1995 and 1996 study periods.

TABLE 17: Mean and percent of adult (aged  $\geq$  18 years), peritoneal dialysis patients with serum albumin  $\geq$  3.5 gm/dL (BCG method) or  $\geq$  3.2 gm/dL (BCP method), Nov '96 - Apr '97, by patient characteristics. 1997 ESRD Core Indicators Project.

	BCG		ВСР		
Patient Characteristic	Mean	% ≥ 3.5 gm/dl	Mean	% ≥ 3.2 gm/dl	
TOTAL	3.5	54	3.3	60	
GENDER Men	3.6	60	3.4	64	
Women	3.4	47	3.2	54	
RACE American Indian/Alaska Native	3.0	0	3.0	0	
Asian/Pacific Islander	3.5	38	3.5	71	
African-American	3.4	49	3.4	66	
Caucasian	3.5	56	3.2	56	
Other/Unknown	3.6	55	3.4	68	
AGE GROUP (years) 18-44	3.6	64	3.4	68	
45-64	3.5	53	3.3	58	
65+	3.4	45	3.2	53	
DIAGNOSIS Diabetes Mellitus	3.4	42	3.1	44	
Hypertension	3.6	60	3.4	71	
Glomerulonephritis	3.6	66	3.4	65	
Other/Unknown	3.5	58	3.3	65	

FIGURE 34: Distribution of serum albumin values for adult (aged ≥ 18 years), peritoneal dialysis patients, Nov '96-Apr '97, by laboratory method\*. 1997 ESRD Core Indicators Project.



\* BCG=Bromcresol green; BCP=Bromcresol purple

FIGURE 35: Adult (aged  $\geq$  18 years), peritoneal dialysis patients with mean serum albumin  $\geq$  3.5 gm/dL (BCG method) or  $\geq$  3.2 gm/dL (BCP method), Nov '96-Apr '97, by race and gender. 1997 ESRD Core Indicators Project.

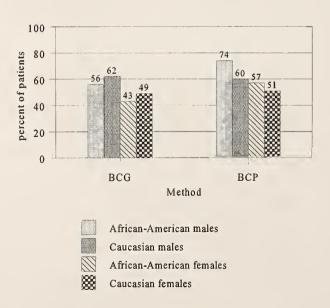
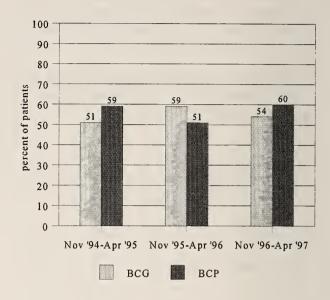


FIGURE 36: Percent of adult (aged ≥ 18 years), peritoneal dialysis patients with mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), Nov '96-Apr '97 compared to Nov '94-Apr '95 and Nov '95-Apr '96. 1997 ESRD Core Indicators Project.



#### E. BLOOD PRESSURE CONTROL

## 1. November 1996-April 1997

The mean systolic and diastolic blood pressure values for adult peritoneal dialysis patients during this study period were 137 mmHg and 80 mmHg, respectively. The distribution of systolic and diastolic blood pressure values for these patients is shown in Figures 37 and 38, respectively.

The percent of these patients with a mean systolic blood pressure > 150 mmHg or diastolic blood pressure > 90 mmHg, which may be a measure for inadequately controlled hypertension, by gender, race, age group and diagnosis, is shown in Table 18. The overall prevalence of inadequately controlled hypertension (by the diastolic measure) was 16%; this prevalence was higher for men compared to women, African-Americans compared to Caucasians, and patients 18-44 years old compared to older patients (TABLE 18).

FIGURE 37: Distribution of systolic blood pressure values for adult (aged  $\geq 18$  years), peritoneal dialysis patients, Nov '96-Apr '97. 1997 ESRD Core Indicators Project.

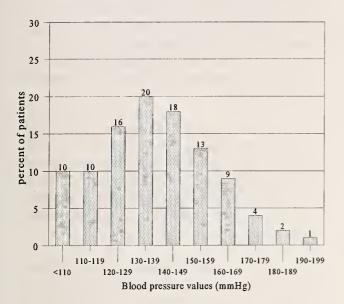


FIGURE 38: Distribution of diastolic blood pressure values for adult (aged ≥ 18 years), peritoneal dialysis patients, Nov'96-Apr '97. 1997 ESRD Core Indicators Project.

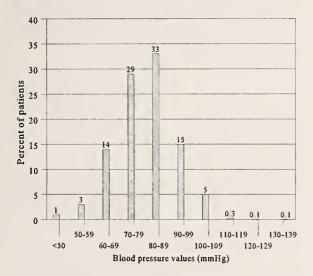


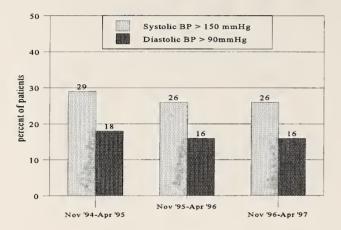
TABLE 18: Mean blood pressure (BP) value and percent of adult (age ≥ 18 years), peritoneal dialysis patients with systolic BP > 150 mmHg or diastolic BP > 90 mmHg, Nov '96-Apr '97, by patient characteristics. 1997 ESRD Core Indicators Project.

		stolic BP mmHg)	Diastolic BP (mmHg)		
Patient Characteristic	Mean	% > 150	Mean	% > 90	
TOTAL	137	26	80	16	
GENDER		! 1 1 1			
Male	139	28	81	20	
Female	135	24	79	12	
RACE		 			
American Indian/	141		70		
Alaska Native	141	0	78	0	
Asian/Pacific Islander	134	24	79	6	
African-American	140	30	84	24	
	137	25	78	13	
Caucasian	136	26	80	15	
Other/Unknown					
AGE GROUP (yrs)					
18-44	135	23	85	29	
45-64	139	29	81	16	
65+	137	26	74	3	
DIAGNOSIS					
Diabetes Mellitus	142	36	78	12	
Hypertension	137	24	81	18	
Glomerulonephritis	136	22	82	20	
Other/Unknown	133	19	80	17	

## 2. November 1996-April 1997 compared to previous study years

There was no clinically important change or improvement in the proportion of adult peritoneal dialysis patients with hypertension over the three study periods (FIGURE 39).

FIGURE 39: Percent of adult (aged ≥ 18 years), peritoneal dialysis patients with mean blood pressure values > 150 (systolic) or > 90 (diastolic) mmHg, Nov '96-Apr '97. 1997 ESRD Core Indicators Project.



#### 1998 Data Collection Effort

In 1998, we will again collect data for these ESRD Core Indicators on a national sample of adult incenter hemodialysis and peritoneal dialysis patients. Any questions about the Project can be addressed to your ESRD Network staff or to members of the ESRD Core Indicators Workgroup (Appendices 1 & 2).

#### VIII. IMPORTANT NOTE

The data in this report are intended to stimulate the development of quality improvement (QI) projects in dialysis facilities. The data collected for this project were necessarily limited: not all dialytic parameters that influence patient care for these clinical measures were collected. In addition, the project did not attempt to develop facility specific profiles of care.

During 1998, we plan to provide a series of supplemental reports. In these reports we will provide more detailed analysis using data collected for the ESRD Core Indicators Project as well as other data from which we can derive information about the patients in the sample identified for this project.

As you review these data, ask yourself questions about how your patients' clinical characteristics compare to these national hemodialysis and peritoneal dialysis patient profiles and Network hemodialysis patient profiles. Additional information must be collected at your facility if you wish to answer these questions and develop ways to improve patient care for your patients. Your ESRD Network staff and Medical Review Board members are available to assist you in using these data in your QI activities and in developing facility specific QI projects.

## IX. APPENDICES

## **Appendix 1.** 1997 ESRD Core Indicators Workgroup Members:

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## Appendix 2. HCFA OFFICES AND ESRD NETWORKS

## **HCFA Offices**

Office of Clinical Standards and Quality Quality Measurement and Health Assessment Group S2-11-07 7500 Security Boulevard Baltimore, MD 21244 (410) 786-5785

Health Care Financing Administration - Region I Division of Health Standards and Quality, Medical Review Branch Room 2275 JFK Federal Building Boston, MA 02203-0003 (617) 565-3136

Health Care Financing Administration - Region VII Division of Health Standards and Quality, Medical Review Branch
New Federal Office Building
601 East 12th Street, Room 242
Kansas City, MO 64106-2808
(816) 426-5746

## **ESRD Networks**

ESRD Network Organization No. 1 ESRD Network of New England P.O. Box 9484 New Haven, CT 06534 Region I: ME, NH.VT, MA, CT, RI (203) 387-9332

ESRD Network Organization No. 2 1216 Fifth Ave New York, NY 10029 Region I: NY (212) 289-4524

ESRD Network Organization No. 3 Cranbury Plaza 2525 Route 130 - Bldg C Cranbury, NJ 08512-9595 Region I: NJ, PR, VI (908) 395-5544 Health Care Financing Administration - Region VI CSQ Room 833 1301 Young St Dallas, TX 75202 (214) 767-4405

Health Care Financing Administration - Region X Division of Health Standards and Quality, Medical Review Branch 2201 Sixth Avenue, Mail Stop (RX-42) Seattle, WA 98121-2500 (206) 615-2317

ESRD Network Organization No. 4 University of Pittsburgh Medical Center 200 Lothrop St. Pittsburgh, PA 15213-2582 Region I: PA, DE (412) 647-3428

ESRD Network Organization No. 5 Mid-Atlantic Renal Coalition 1527 Huguenot Road Midlothian, VA 23113 Region I: DC, MD, VA, WV (804) 794-3757

ESRD Network Organization No. 6 Lake Plaza East 900 Ridgefield Dr., Suite 150 Raleigh, NC 27609 Region VI: GA, NC, SC (919) 876-7545

## Appendix 2 - HCFA Offices and ESRD Networks

ESRD Network Organization No. 7 ESRD Network of Florida, Inc. 1 Davis Boulevard, Suite 304 Tampa, FL 33606 Region VI: FL (813) 251-8686

ESRD Network Organization No. 8 Network Eight, Inc. P.O. Box 55868 Jackson, MS 39296-5868 Region VI: AL, MS. TN (601) 936-9260

ESRD Network Organization No. 9 & 10 Tri-State Renal Network, Inc. 911 East 86th Street, Suite 202 Indianapolis, IN 46240-1858 Region VII: KY, IN, OH, IL (317) 257-8265

ESRD Network Organization No. 11 ESRD Renal Network of the Upper Mid-West, Inc. 970 Raymond Avenue, Suite 205 St. Paul, MN 55114 Region VII: MI, MN, WI, ND, SD (612) 644-9877

ESRD Network Organization No. 12 Northpoint Circle II, Suite 105 7509 NW Tiffany Springs Parkway Kansas City, MO 64153 Region VII: MO. IA, NE, KS (816) 880-9990

ESRD Network Organization No. 13 6600 N Meridan Ave, Ste 155 Oklahoma City, OK 73116-1421 Region VI: AR, LA, OK (405) 843-8688 ESRD Network Organization No. 14 ESRD Network of Texas, Inc. 14114 Dallas Parkway, # 660 Dallas, TX 75240 Region VI: TX (972) 503-3215

ESRD Network Organization No. 15 Intermountain ESRD Network, Inc. 1301 Pennsylvania Street, Suite 220 Denver, CO 80203-5012 Region X: NM, CO, WY, UT, AZ, NV (303) 831-8818

ESRD Network Organization No. 16 Northwest Renal Network 2701 First Avenue, Suite 430 Seattle, WA 98121 Region X: MT, AK, ID, OR, WA (206) 448-1803

ESRD Network Organization No. 17 25 Mitchell Blvd Suite 7 San Rafael, CA 94903 Region X: No. CA, HI, Pacific Trust Territory, GU, AS (415) 472-8590

ESRD Network Organization No. 18 Southern California Renal Disease Council 6255 Sunset Boulevard, Suite 2211 Los Angeles, CA 90028 Region X: So. CA (213) 962-2020

## IN-CENTER HEMODIALYSIS (HD) CORE INDICATORS DATA COLLECTION FORM: 1997

BEFORE COMPLETING FORM, READ INSTRUCTIONS ON BACK OF FORM PATIENT IDENTIFICATION MAKE CORRECTIONS TO PATIENT INFORMATION ON LEFT IN THE SPACE BELOW PLACE LABEL HERE I0.a Is patient Hispanic? Unknown 11. IS THE ABOVE PATIENT INFORMATION CORRECT - Please verify race and check question 10 a. above. YES; Go to question 12. NO; Make corrections above, then go to question 12. UNKNOWN; STOP. Note the provider if known & return form to Network 12. Patient's height: inches or centimeters LAB DATA. The following data are requested for OCT, NOV and DEC, 1996. For each question, use the FIRST LAB VALUES OF THE MONTH. Do not leave any questions blank. ENTER THE FOLLOWING CODES IN THE SPACES BELOW IF LAB VALUES CANNOT BE LOCATED: NF if Not Found, HOSP if patient was hospitalized during the entire month, TRANS if patient was absent during the entire month. NP if tests not performed at any time during the month. OCT 1996 NOV 1996 **DEC 1996** 13. HEMATOCRIT: Enter the FIRST monthly HCT determined by the LABORATORY for EACH MONTH: OCT, NOV, DEC 1996. DO NOT ENTER SPUN HCT VALUE unless your facility does not obtain lab hcts. Also enter the prescribed WEEKLY EPO dose and the route of administration; the first monthly Ferritin and Transferrin Saturation value and the route of iron administration. A. First monthly pre-dialysis laboratory hematocrit: B. Was a prescription for EPO in effect (EVEN IF patient did not receive dose) during the WEEK the monthly het above was drawn? C. If yes, what was the PRESCRIBED WEEKLY EPO dose at the \_\_ units/wk units/wk units/wk time immediately before the above HCT was drawn? D. What was the prescribed route of EPO administration? IV \_\_\_\_ E. First monthly Ferritin value. F. First monthly Transferrin Saturation value. % % % G. Was a prescription for Iron in effect during the month? No No P.O. H. If yes, what was the route of iron administration? (check all apply) IV \_\_ P.O. IV \_ P.O. IV 14. BUN: Enter the first monthly pre and post dialysis BUN FOR EACH MONTH: OCT, NOV, DEC 1996. The pre- and post-dialysis BUNs must be drawn on the same day of the month. If only performed quarterly, enter the FIRST values for month performed and enter "NP" for the other two months. Also, enter the patient's actual DELIVERED time on dialysis when the BUNs were drawn and the CODE for the name of the dialyzer used at the time the BUNs were drawn. (See attached chart for the dialyzer codes.) A. First monthly Pre dialysis BUN: \_mg/dl \_mg/dl \_mg/dl B. First monthly Post dialysis BUN: mg/dl \_mg/dl mg/dl C. Patient's PRE & POST dialysis weight when BUNs Pre: \_\_\_\_ lbs/kgs \_lbs/kgs \_lbs/kgs above drawn: (Circle either lbs or kgs) lbs/kgs Post: lbs/kgs lbs/kgs D. Actual DELIVERED time on dialysis at session when BUNsdrawn: min E. Code for dialyzer used at session when BUNs drawn (see chart): 15. SERUM ALBUMIN: Enter the FIRST monthly serum albumin FOR EACH MONTH: OCT, NOV, DEC 1996. Check the method used by lab to determine the serum albumins. If method unknown, please call lab to find out. Do not leave blank, A. First monthly serum albumin: gm/dl gm/dl gm/dl B. Check lab method used (BCG=bromcresol green; BCGreen BCGreen **BCGreen** 

**BCPurple** 

BCP=bromcresol purple):

16. Name, title and phone number of individual completing form:

**BCPurple** 

**BCPurple** 

## Appendix 3 continued

## Page 56

## INSTRUCTIONS FOR COMPLETING THE IN-CENTER HD CORE INDICATORS DATA COLLECTION FORM - 1997

If the information is incorrect, make corrections to the right of the label. The label on the top left side of the form (#'s 1-8) contains the following patient identifying information.

- LAST and first name.
- 3. SOCIAL Security Number (SSN).
- 5. SEX (M=Male; F=Female; U=Unknown). 6=American Indian/Alaskan Native.
- DATE of birth (DOB) as MM/DD/YYYY.
   HEALTH Insurance Claim Number (HIC).
- 6. RACE (0=Unknown; 1=White; 2=Black; 3=Other; 4=Asian/Pacific Islander;
- 7. PRIMARY cause of renal failure by HCFA-2728 code.
- B. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.
- 9. ESRD Network number: Do not make corrections to this item. 10. Facility's Medicare provider number.
- 10a. Is patient Hispanic? Please check either Yes, No, or Unknown, as appropriate.
- 11. Review the patient and facility specific information contained on the pre-printed label (Please verify the patient's race, question no. 6 above, and check question 10 a.) and mark either Yes, No or Unknown. If No is marked, write corrections to the pre-printed information in the space to the right of the label. If Unknown is marked, send the form back to the ESRD Network office with the name and address of the facility providing services to this patient on December 31, 1996, if known.

To answer questions 12 - 15, review the patient's medical record for the months of October through December 1996. Do not leave any items blank. Enter the following codes if the information cannot be located: "NF" for not found, "HOSP" if the patient was hospitalized during the entire month, "TRANS" if patient was absent during the entire month, "NP" if test not performed at any time during the month.

- 12. Enter the patient's height in inches or centimeters. You may ask the patient his/her height to obtain this information.
- 13 A. Enter the patient's FIRST MONTHLY pre-dialysis hematocrit (HCT) value determined by the laboratory's Coulter Counter or other hematology instrument for EACH month October, November and December 1996. DO NOT record any spun HCT value performed by the dialysis facility UNLESS YOUR FACILITY DOES NOT OBTAIN LABORATORY HEMATOCRIT LEVELS.
- 13B. Check the appropriate space to indicate if there was a prescription for EPO in effect during the WEEK the monthly HCT was drawn, even if the patient did not receive the EPO dose.
- 13C. If the answer to 13B. is yes, please enter the PRESCRIBED WEEKLY EPO dose at the time immediately before the monthly HCT was drawn. If prescribed other than weekly, divide the EPO dose by the number of weeks prescribed to obtain weekly EPO dose OR if using a sliding scale for EPO dosing or giving EPO at each treatment, total all the doses given during the week and enter this value.
- 13D. Check the appropriate space to indicate the route of administration for EPO (intravenously (IV) or subcutaneous (SC)).
- 13E. Enter the patient's FIRST MONTHLY ferritin value recorded EACH month for October, November and December 1996. If a Ferritin test is not performed monthly, enter the value for the month when performed and record "not performed" for the other month(s).
- 13F. Enter the patient's FIRST MONTHLY transferrin saturation value recorded EACH month for October, November and December 1996. If an transferrin saturation test is not performed monthly, enter the value for the month when performed and record "not performed" for the other month(s).
- 13G. Check the appropriate space (yes or no) to indicate if there was a prescription for Iron in effect at any time during each month of October, November and December 1996.
- 13H. If the answer to 13G. is yes, please check the appropriate space to indicate the route of iron administration (intravenously (IV) or by mouth (P.O.)) each month. If patient received iron by mouth and IV, check both spaces.
- 14A, Enter the patient's FIRST pre and post dialysis BUN values recorded EACH month for October, November and December 1996. The BUN values
- B must be drawn on the same day. If pre and post dialysis BUNs are only performed quarterly, enter the values for the month when performed and record "not performed" for the other two months.
- 14C. Enter the patient's PRE & POST dialysis weight at the session when the pre and post dialysis BUN levels were drawn; circle either lbs or kgs as appropriate.
- 14D. Enter the patient's ACTUAL DELIVERED time on dialysis during the session when the BUN levels were drawn. DO NOT ENTER THE PRESCRIBED TIME ON DIALYSIS.
- 14E. Using the enclosed Dialyzer Code Chart, enter the code for the dialyzer used on the day the blood samples were drawn for the pre and post dialysis BUNs in October, November and December 1996. If the dialyzer used is not on the chart, enter the code for other (9999).
- 15A. Enter the patient's FIRST serum albumin value recorded EACH month for October, November and December 1996.
- 15B. Check the appropriate method used by the laboratory to determine the serum albumin levels (bromeresol green or bromeresol purple). If you do not know what method the laboratory used, call the laboratory to find out this information. DO NOT LEAVE THIS QUESTION BLANK.
- 16. Enter the name, title and phone number of the person who completed the form. Forward the completed form to your ESRD Network office. HCFA-820 (rev, 03/97)

  HCFA/HSQB & NIH/NIDDK(NIH-CE950202A)

#### PERITONEAL DIALYSIS CORE INDICATORS DATA COLLECTION FORM: 1997 BEFORE COMPLETING FORM, PLEASE READ INSTRUCTIONS ON PAGES 3 & 4 PATIENT IDENTIFICATION MAKE CORRECTIONS TO PATIENT INFORMATION ON LEFT IN THE SPACE BELOW PLACE LABEL HERE 10.a Is patient Hispanic? \_\_\_\_ Yes, 11. If the above patient information is incorrect, make corrections in space above, then continue to question 12. Please verify the patient's race and check question 10 a. above. If patient unknown or was not dialyzed in the unit at any time during Nov - Dec 1996 & Jan - Apr 1997, return the form to the Network. inches centimeters 13. Does patient have limb amputation(s): 12. Patient's height (MUST COMPLETE): No LAB DATA. The following data are requested for the 2-MONTH TIME PERIODS NOV-DEC 1996, JAN-FEB 1997, & MAR-APR 1997. For each question, where appropriate use the 1st Lab values obtained during each of the 2-Month Time Periods. ENTER THE FOLLOWING CODES IN THE SPACES BELOW IF LAB VALUES CANNOT BE LOCATED: NF if Not Found, HOSP if patient was Hospitalized during the entire time period; TRANS if patient absent during the entire time period. NP if tests Not Performed at any time during the time period. NOV - DEC 1996 JAN - FEB 1997 MAR - APR 1997 14. ADEQUACY: Enter the 1ST monthly adequacy measurements/results listed below that were obtained FOR EACH 2-MONTH time period: NOV-DEC 1996, JAN - FEB 1997, MAR-APR 1997. ONLY enter those tests performed. Please read instructions on pages 3 & 4 before completing this section CAPD; \_\_\_ CCPD; CAPD; \_\_\_ CCPD; CAPD; \_\_\_ CCPD; A. Check all the dialysis modality(s) the patient was on during each 2month time period: HEMO; IPD HEMO; \_\_\_ IPD HEMO; \_\_\_ IPD B. Patient weight at 1st adequacy assessment for 2-month time period: (Circle either lbs or kgs) kgs CAPD; \_\_\_ CCPD; CAPD; CCPD; CAPD; CCPD; C. Patient's dialysis modality when adequacy measures below were performed. IPD IPD IPD D. 1st 24 hr DIALYSATE outflow volume for 2-month time period: ml ml ml E. 1st 24 hr DIALYSATE urea nitrogen for 2-month time period: \_mg/dl \_mg/dl \_mg/dl F. 1st 24 hr DIALYSATE creatinine for 2-month time period: mg/dl mg/dl \_mg/dl 1st 24 hr URINE volume for 2-month time period: \_ ml ml ml (If 24 hr urine was not collected check NP. If patient is anuric, check anuric and go to question 14. J.) NP NP anuric H. Ist 24 hr URINE urea nitrogen for 2-month time period: mg/dl mg/dl mg/dl I. 1st 24 hr URINE creatinine for 2-month time period: mg/dl \_mg/dl mg/dl J. SERUM BUN at 1st adequacy assessment for 2-month time period: \_mg/dl \_mg/dl mg/dl K. SERUM creatinine at 1st adequacy assessment for 2-month period: mg/dI \_mg/dl mg/dl L. 1st weekly Kt/V urea for each 2-month time period: M. Method by which V above was calculated (check one): %BW \_\_ %BW \_\_ %BW Hume Hume Hume (See instructions on page 4) Watson Other Watson Other Watson Other

N. 1st weekly creatinine clearance for each 2-month time period:

O. Is creatinine clearance corrected for body surface area?

L/wk

L/wk

\_ No

Yes \_

L/wk

PERITONEAL DIALYSIS CORE INDICA	ATORS DATA COLLECT	ION FORM: 1997 CON	NTINUED
	NOV - DEC 1996	JAN - FEB 1997	MAR - APR 1997
15. PERITONEAL DIALYSIS PRESCRIPTION: For the following ques recorded in Q 14 were performed. If adequacy measures/results were not medical record for each 2-month time period. Complete all items that are prescription category. MUST be completed for each 2-month time period.	performed in each 2-month time applicable. Please read instruction	period, record the first PD pre ns on page 4-before completi	scription found in the
CAPD PRESCRIPTION:  A. Prescribed dwell volume for a SINGLE exchange:	ml	ml	ml
B. Prescribed number of exchanges per 24 hrs:			
CYCLER NIGHT TIME PRESCRIPTION (for IPD & CCPD only): C. Prescribed dwell volume for a SINGLE exchange:	ml	ml	mî
<ul> <li>D. Prescribed number of nighttime exchanges per 24 hrs:</li> <li>E. Prescribed dwell time for a SINGLE exchange (average time if varied):</li> </ul>	min	min	min
CYCLER DAY TIME PRESCRIPTION (for CCPD only): F. Prescribed dwell volume for a SINGLE exchange:	ml	ml	ml
<ul> <li>G. Prescribed number of daytime exchanges per 24 hrs:</li> <li>H. Prescribed dwell time for a SINGLE exchange (average time if varied):</li> </ul>	min	min	min
16. Peritoneal Equilibration Test (PET): Enter in this section only the calc outside the 6-month time frame, if necessary, to respond to the following of		tio. Refer to records in the pa	tient's medical chart
A. Most recent four hour PET test result for D/P creatinine:	Date o	f this test result:/_	
LAB DATA. The following data are requested for the 2-MONTH TIME PE appropriate use the 1st 1 show here obtained during each of the 2-Month Time CANNOT BE LOCATED: NF if Not Found, HOSP if patient was Hospi period, NP if tests Not Performed at time during the time period.	Periods. ENTER THE FOLLOW	VING CODES IN THE SPA	CES BELOW IF LAB VALUE
	NOV - DEC 1996	JAN - FEB 1997	MAR - APR 1997
<ol> <li>HEMATOCRIT: Enter the FIRST HCT determined by lab's Coulter Co. 1996, JAN-FEB 1997, MAR-APR 1997. DO NOT ENTER SPUN HC</li> </ol>			time period: NOV-DEC
A. 1st laboratory hematocrit obtained for 2-month time period:	%	%	%
B. Was a prescription for EPO in effect (EVEN IF patient did not receive dose) during the week the monthly het above was drawn?	YesNo	YesNo	Yes No
C. If yes, what was the PRESCRIBED WEEKLY EPO dose at the time immediately before the above HCT was drawn?	units/wk	units/wk	units/wk
D. First Transferrin Saturation value obtained for 2-month time period.			%
E. First Ferritin value obtained for 2-month time period.	ng/mL	ng/mL	ng/mL
F. Was a prescription for Iron in effect during the 2-month time period?	Yes No	Yes No	YesNo
G. If yes, what was the route of administration? (check all that apply)	IVP.O.	IV P.O.	IV P.O.
18 SERUM ALBUMIN: Enter the 1ST serum albumin obtained FOR EAG the method used by lab to determine the serum albumins. If method unkn	CH 2-MONTH time period: NOV own, please call lab to find out. D	7-DEC 1996, JAN-FEB 1997 to not leave blank.	, MAR-APR 1997. Check
A. 1st serum albumin obtained for 2-month time period:	gm/dl	gm/dl	gm/dl
B. Check lab method used (BCG=bromcresol green; BCP=bromcresol purple):	BCGreen BCPurple	BCGreen BCPurple	BCGreen BCPurple
<ol> <li>BLOOD PRESSURE: Enter the 1ST monthly upright BP (systolic/dias MAR- APK 1997. If the SBP or the DBP was unobtainable, enter UNOE</li> </ol>			IAN-FEB 1997,
First monthly upright BP: (SBP/DBP)			

#### Appendix 4 continued Page 59

#### INSTRUCTIONS FOR COMPLETING THE PERITONEAL DIALYSIS CORE INDICATORS DATA COLLECTION FORM - 1997

The label on the top left side of the form (#'s 1-8) contains the following patient identifying information. If the information is incorrect, make corrections to the right of the label.

- LAST and first name.
   DATE of birth (DOB) as MM/DD/YYYY.
- 3. SOCIAL Security Number (SSN). 4. HEALTH Insurance Claim Number (HIC).
- 5. SEX (M=Male; F=Female; U=Unknown). 6. RACE (0=Unknown; 1=White; 2=Black; 3=Other; 4=Asian/Pacific Islander,
  - 6=American Indian/Alaskan Native. 7. PRIMARY cause of renal failure by HCFA-2728 code.
- B. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.
- 9. ESRD Network number: Do not make corrections to this item.
- 10. Facility's Medicare provider number 10a. Is the patient Hispanic? Check either Yes, No, or Unknown, as appropriate.
- 1. Review the patient and facility specific information contained on the pre-printed label. Please verify the patient's race, question no. 6 above, and check question 10a. If any of the information is incorrect, write corrections in the space to the right of the label. If the patient is unknown or if the patient was not dialyzed in the unit at any time during Nov Dec 1996 & Jan Apr 1997, send the form back to the ESRD Network office with the name and address of the facility providing services to this patient on April 30, 1997, if known.

To answer questions 12 - 19, review the patient's clinic or facility medical record for each two month time period: NOV-DEC 1996; JAN-FEB 1997; & MAR-APR 1997. Do not leave any items blank. Enter the following codes if the information cannot be located: NF for not found, HOSP if patient hospitalized during the entire time period, TRANS if patient was absent during the entire time period, NP if tests not performed at any time during the time period. For question 16, you may need to refer to information in the patient's medical record that is outside this six month time period.

- 12. Enter the patient's height in inches or centimeters. HEIGHT MUST BE ENTERED, do not leave this field blank, you may ask the patient his/her height to obtain this information. If patient had both legs amputated, record pre-amputation height and check YES for question no. 13.
- 13. Check either YES or NO if the patient had arm or leg amputation (s).
- 14. Enter the FIRST dialysis adequacy measurements that were obtained for each 2 month time period. YOU MAY NOT HAVE DATA ON THESE TESTS FOR EACH 2-MONTH TIME PERIOD. If the adequacy measurements were only performed quarterly or each 6-months, enter the first adequacy measurements for each 2-month period and enter "NP" (for not performed) for any other 2-month interval. IF THE PATIENT WAS ON HEMODIALYSIS DURING THE ENTIRE 2-MONTH TIME PERIOD MARK QUESTIONS 14. B-N, HEMO.
- 14A. Check the modality the patient was on during each 2-month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997. CHECK either CAPD, CCPD, HEMO or IPD. If the patient was on more than one modality during the 2-month time period, check all applicable modalities. IPD patients are those with CYCLER NIGHTTIME PRESCRIPTIONS only. CCPD patients are those with BOTH CYCLER NIGHTTIME AND CYCLER DAYTIME PRESCRIPTIONS (see definitions under number 15)
- 14B Enter the patient's weight at the clinic/facility visit when the adequacy measurements were obtained, circle lbs or kgs as appropriate.
- 14.C. Check the modality the patient was on during each 2-month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997 when the adequacy measures in questions 14 D N were performed. If adequacy measures were not performed during the 2-month time period, enter NP and skip questions 14 D O.
- 14D Enter the FIRST 24 hr DIALYSATE outflow volume, urea nitrogen and creatinine obtained for each 2-month time period: Nov-Dec 1996; Jan-
- & F. Feb 1997; & Mar-Apr 1997. If a 24 hr dialysate outflow volume, urea nitrogen and creatinine were NOT measured at any time during each of these 2-month time periods, enter NP (for not performed) in the appropriate 2-month time period spaces. ONLY ENTER ACTUAL MEASURED 24 HOUR DIALYSATE VOLUME. DO NOT ENTER AN EXTRAPOLATED DIALYSATE VOLUME. The outflow volume consists of the 24 hr dialysate infused volume PLUS the 24 hr ultrafiltration volume.
- 14G. Enter the FIRST 24 hr URINE volume obtained for each 2-month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997. ONLY ENTER ACTUAL MEASURED 24 HR URINE VOLUME DO NOT ENTER AN EXTRAPOLATED URINE VOLUME. If 24 hr urine volume was not measured check NP for not performed OR if the patient is anuric, check anuric. If NP or anuric is checked, SKIP TO QUESTION 14. J.
- 14H Enter the FIRST urine urea nitrogen and creatinine obtained for each 2-month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997. If
- & I. urine urea nitrogen and creatinine were only measured quarterly or each 6-months, enter the FIRST value obtained for each 2-month time period and enter NP for any 2-month time period when not performed.
- 14 J Enter the SERUM BUN and SERUM CREATININE obtained at 1st adequacy assessment for each 2-month time period: Nov-Dec 1996; Jan-Feb
- & K 1997; & Mar-Apr 1997. If adequacy assessment measurements are only obtained quarterly or each 6-months, enter serum BUN and creatinine results for the corresponding dialysate data in 14 D-F and enter NP in the appropriate spaces for any 2-month time period when not performed.
- 14 L Enter the FIRST WEEKLY Kt/V UREA and/or WEEKLY CREATININE CLEARANCE for each 2 month time period: Nov-Dec 1996; Jan-Feb
- &N 1997; & Mar-Apr 1997. NOTE: If you have a value for weekly Kt/V urea (or creatinine clearance) for a particular two month period, please complete the corresponding values for questions 14 D-K for 24 hour dialysate volume, 24 hour dialysate urea (or creatinine) and, if the patient is not anuric, the 24 hour urine urea (or creatinine), if these values are available. If Kt/V or creatinine clearance results were only measured quarterly or each 6-months, enter the FIRST value obtained for each 2-month time period and enter NP for any 2-month time period when not performed. If your unit calculates a daily Kt/V or daily creatinine clearance, multiply this result by 7.0 and enter the result in the appropriate space(s).

## Appendix 4 continued

- Page 60
- 14M. Check the method used to calculate the V in the Kt/V measurement; % BW = percent of body weight; Hume and Watson are two nomograms used to calculate V based on several of these parameters weight, height, age, gender. If method used to calculate V is not known, please call lab to ascertain method. Please do not leave blank.
- 14O. Check Yes or No if the weekly creatinine clearance was normalized for body surface are (i.e., the result is multiplied by the patient's body surface area (BSA) and divided by 1.73m2). If you do not have this information, call the laboratory that provided the weekly Kt/V urea or creatinine clearance value for this information.
- 15. To respond to questions 15. A H, record the peritoneal dialysis (PD) prescription in effect at the time the adequacy measures/results you recorded in question 14 were performed. If adequacy measures/results were not performed in each 2-month time period Nov-Dec 1996, Jan-Feb 1997 & Mar-Apr 1997, record the first PD prescription found in the medical record for each 2-month time period. Complete all items that are applicable. If the patient was on hemodialysis for an entire 2-month time period, record HEMO in blanks. ONE PD PRESCRIPTION CATEGORY MUST BE COMPLETED FOR EACH 2-MONTH TIME PERIOD, unless the patient was on hemodialysis for the entire 2-month time period.
- 15A CAPD PRESCRIPTION. Use the CAPD prescription category for CAPD patients only. Enter the <u>dwell volume</u> for a single exchange and & B <u>number of exchanges per 24 hour period</u> **PRESCRIBED** for CAPD at the time the adequacy measures in question 12 were performed during each 2 month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997. If the patient was not on CAPD during the entire two month period, enter NP.
- 15C,D CYCLER NIGHTTIME PRESCRIPTION. Use the CYCLER NIGHTTIME prescription category for IPD and CCPD patients only. Enter the & E. dwell volume for a single exchange, number of nighttime exchanges per 24 hour period and dwell time for a single exchange (record average time if varied). PRESCRIBED for CYCLER NIGHTTIME at the time the adequacy measures in question 12 were performed during each 2 month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997. Include in the CYCLER NIGHTTIME prescription only those exchanges provided by an automated device. DO NOT include in this category any wet day prescriptions (i.e., a last dwell fill that the patient carries after unhooking from the cycler or any daytime dwells) as these exchanges are recorded in the CYCLER DAYTIME prescription below.
- 15F.G CYCLER DAYTIME PRESCRIPTION. Use CYCLER DAYTIME prescription category for CCPD patients only. Enter the <u>dwell\_volume</u>,
- & H. for a single exchange, number of daytime exchanges per 24 hour period and dwell time for a single exchange (record average time if varied)

  PRESCRIBED for CYCLER DAYTIME at the time the adequacy measures in question 12 were performed during each 2 month period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997. INCLUDE in the CYCLER DAYTIME prescription only those exchanges performed after the patient disconnects from the cycler and/or a last dwell fill that the patient carries during the day. (e.g., WET DAY PRESCRIPTION). ANY OTHER EXCHANGES PERFORMED USING THE CYCLER SHOULD BE INCLUDED UNDER CYCLER NIGHTTIME PRESCRIPTION.
- 16.A Enter the MOST RECENT Peritoneal Equilibration Test (PET) results for D/P creatinine and the date the test was performed. The test result and corresponding date performed may be outside the 6-month time frame. If never performed enter NP.
- 17.A Enter the patient's FIRST hematocrit (HCT) value determined by the laboratory's Coulter Counter or other hematology instrument for EACH 2-month time period: Nov-DEC 1996; Jan-Feb 1997; & Mar-Apr 1997. DO NOT record any spun HCT value performed by the dialysis facility UNLESS YOUR FACILITY DOES NOT OBTAIN LABORATORY HEMATOCRIT LEVELS.
- 17B. Check the appropriate space to indicate if there was a prescription for EPO in effect during the week the monthly HCT was drawn, EVEN IF the patient did not receive the EPO dose.
- 17C. If the answer above is yes, please enter the **PRESCRIBED WEEKLY** EPO dose at the time immediately before the monthly HCT was drawn. If prescribed other than weekly, divide the EPO dose by the number of weeks prescribed to obtain weekly EPO dose OR if using a sliding scale for EPO dosing, total all the doses given during the week and enter this value.
- 17D Enter the first transferrin saturation value obtained for EACH 2-month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997. If not performed enter NP.
- 17E. Enter the first ferritin value obtained for EACH 2-month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997. If not performed enter NP.
- 17F. Check the appropriate space (yes or no) to indicate if there was a prescription for Iron in effect at any time during EACH 2-month time period: Nov-Dec 1996; Jan-Feb 1997: & Mar-Apr 1997.
- 17G. If the response to 17. F. is yes, please check the appropriate space to indicate the route of iron administration, (intravenously (IV) or by mouth (P.O.)) for each 2-month time period. If the patient received iron by mouth and IV, check both spaces.
- 18A. Enter the patient's FIRST serum albumin value recorded for EACH 2-month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997.
- 18B. Check the appropriate method used by the lab to determine the serum albumin levels (bromcresol green or bromcresol purple). If you do not know what method the lab used, please call the lab to find out this information; DO NOT LEAVE THIS QUESTION BLANK.
- 19. Enter the patient's FIRST monthly upright blood pressure (systolic and diastolic) for EACH 2-month time period: Nov-Dec 1996; Jan-Feb 1997; & Mar-Apr 1997. Use clinic/facility records for BP values. If the SBP or the DBP was unobtainable (as opposed to not recorded or not found in the patient's chart), enter UNOB or P for palpated or D for Doppler in the appropriate space.
- 20. Enter the name and phone number of the person who completed the form & RETURN COMPLETED FORM TO YOUR ESRD NETWORK.

## Appendix 5. References

- Consensus Development Conference Panel.
   Morbidity and mortality of renal dialysis: An NIH consensus conference statement. Ann Intern Med, 1994; 121:62-70.
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